4-20-09 IFW AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Applicants:	SHANKS, Steven C. and TUCEK, Kevin B.
Title of Invention:	Multi-Probe Device
Filed:	July 1, 2003
Serial Number:	10/612,504
Atty Docket No.:	206-038

Examiner: Henry M. Johnson, III
Art Unit: 3739

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AnnMarie Whitley
AnnMarie W. Whitley

Express Mail Number: EH 450493105 US

REPLY BRIEF

Mail Stop Appeal Brief
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

An Examiner's Answer was mailed on March 17, 2009, which requires a reply brief to be filed within two months. This Reply Brief is submitted on or before May 17, 2009 and is therefore considered timely filed. No fee is believed due.

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In re Application of
Applicants: SHANKS, Steven C. and TUCEK, Kevin B.
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REPLY BRIEF

Table of Contents

Cases Cited

Continental Can Co. USA Inc. v. Monsanto Co., 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991)

In re Gurley, 27 F.3d 551, 31 USPQ2d 1130 (Fed. Cir. 1994)

In re Icon Health and Fitness, Inc., 496 F.3d 1374, 83 USPQ2d 1746 (Fed. Cir. 2007)

In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981)

In re Schreiber, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997)

In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971)

KSR Int'l Co. v. Teleflex Inc., 550 U.S. ____, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007)

McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 60 USPQ2d 1001 (Fed. Cir. 2001)

MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 52 USPQ2d 1303 (Fed. Cir. 1999)

Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 67 USPQ2d 1664 (Fed. Cir. 2003)

United States v. Adams, 383 U.S. 39,148 USPQ 479 (1966)

Verdegaal Bros, Inc. v. Union Oil Co. of California, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987)

List of References

R-1 U.S. Patent 6,074,411 issued to Lai (referred to herein as "Lai")

R-2 Appeal Brief dated August 2, 2006

R-3 Appeal Brief dated March 5, 2007

R-4 U.S. Patent 6,267,779 issued to Gerdes (referred to herein as "Gerdes")

R-5 U.S. patent 5,653,706 issued to Zavislan (referred to herein as "Zavislan")

R-6 Applicants' Specification of U.S. Patent App. No. 10/612,504, as amended, and Drawings

Copies of the references above are included in the References Cited Appendix

Manual of Patent Examining Procedure, Eighth Edition, August 2001, Rev. 4 October 2005

MPEP §2114

MPEP §2142

I. Reply Arguments

A. Lai Does Not Anticipate Applicants' Claims Under 35 USC 102(b).

The Examiner argues that Applicant's claims 1, 2, 8-10, 13-15, and 22 are anticipated by Lai. In particular, the Examiner argues that:

(1) Lai anticipates Applicants' claimed invention because Lai discloses the structural elements recited in Applicants' claims; and

(2) Lai anticipates Applicants' claimed invention because Lai inherently discloses beam shaping optics and spot shapes.

Applicants continue to respectfully disagree with the Examiner's arguments.

Principles of Law Relating to Anticipation & Inherency

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987).

When determining the elements or limitations of a claim, it is well-established law that a patent applicant can recite features of his invention either structurally or functionally. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); MPEP §2114. When an element is defined functionally, however, it may be anticipated by a prior art structure if the prior art structure inherently discloses the functionally claimed element. *In re Schreiber* at 1478, 44 USPQ2d at 1432 (citing *In re Swinehart*, 439 F.2d 210, 213, 169 USPQ 226, 228 (CCPA 1971)).

The Federal Circuit has explained that, to establish that a characteristic is inherently disclosed by a prior art reference, the inherent characteristic must be a "necessary and inevitable" consequence of the disclosure in a prior art reference.

Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1378-80, 67 USPQ2d 1664 (Fed. Cir. 2003); *Continental Can Co. USA Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). It is not sufficient to show that the prior art would probably, or possibly, produce the undisclosed element. *Continental Can* at 1269, 20 USPQ2d at 1749; see also *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) ("Occasional results are not inherent.").

An instructive example of an inherent anticipation analysis by the Federal Circuit can be found in *MEHL/Biophile.* 192 F.3d at 1362. *In MEHL/Biophile*, a disputed patent claim required that a laser light applicator be aligned substantially vertically over a hair follicle opening. *MEHL/Biophile* at 1364. One of the prior art references was an instruction manual that described the use of a laser to remove tattoos but was silent as to applying the laser to hair follicles and as to vertical alignment therewith. *Id.* at 1364. The Federal Circuit found that the manual did not inherently disclose vertical alignment of the laser light applicator because the operator of the prior art laser could "use the laser according to the manual without necessarily aligning the laser 'substantially vertically over a hair follicle opening.'" *Id.* at 1365. The Federal Circuit explained that "[t]he *possibility* of such an alignment does not legally suffice to show anticipation." *Id.* (citing *In re Oelrich,* 666 F.2d 578, 581 212 USPQ 323, 326 (CCPA 1981) (emphasis added).

1. Lai does not expressly or inherently disclose freely moving probes while emitting laser beams.

Applicants disagree with the Examiner that, because Lai discloses the structural components of Applicants claims, Lai anticipates Applicants' claims. Consistent with the teachings of *In re Schreiber* presented above, Applicants describe an element of their

claimed invention in functional terms: each of two or more handheld probes "emits one or more laser beams . . . while being freely moved by a user's hand relative to the surface of the skin of a patient."[1] The appropriate question then becomes whether the prior art inherently discloses freely moving multiple laser probes while they emit laser beams.

Lai does not inherently disclose freely moving laser probes while they emit laser beams. Lai does not even teach a device capable of being freely moved by hand while emitting laser beams. Rather, Lai emphasizes that its laser modules must be pointed directly at an acupuncture point and that self-adhesive holders are configured to securely hold the laser module at the acupuncture point. *See* Lai, col. 2, lines 21-28. The Examiner asserts that Figure 2 of Lai discloses an embodiment of Lai's laser module that operates without the adhesives. Figure 2, however, simply illustrates the laser module onto which the adhesive holder is applied. *See* Lai, col. 2, lines 21-31 and 57-59. There is nothing in Lai's disclosure that indicates Lai's laser modules are capable of emitting laser beams while they are freely moved.

Even assuming, arguendo, that the laser modules of Lai are considered capable of freely moving during operation, it does not follow that Lai's laser modules *necessarily* emit one or more laser beams while being freely moved by a user's hand. Moreover, freely moving laser probes while they are emitting light is in no way the inevitable result of practicing Lai's invention. The laser modules taught by Lai operate on a timer-controlled switch, which can easily control the laser module so that it only emits laser beams after being placed and secured on the patient's acupuncture sites. *See* Lai, co. 3, lines 11-14. As with the prior art instruction manual in *MEHL/Biophile*, Lai is silent on

[1] *See* Applicants' claim 1.

whether its laser modules are freely movable while emitting laser light. Accordingly, the mere *possibility* that the laser modules disclosed in Lai could be moved while emitting laser light is insufficient to establish inherent anticipation.

Because Lai fails to expressly or inherently disclose handheld probes that are freely moveable during laser operation, Lai cannot anticipate Applicants' claims 1, 2, 8-10, 13-15 and 22.

2. Lai does not expressly or inherently disclose a beam-shaping apparatus or a spot shape.

Applicants respectfully disagree with the Examiner's arguments that Lai teaches the use of optics and that beams inherently must have some shape.

As detailed in Applicants' earlier briefs,[2] Lai discloses only focusing optics. Contrary to the Examiner's assertions, protective lenses and focusing optics do not necessarily or inevitably create beam shapes. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent's skin. A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the resultant shape. Similarly, a protective lens simply protects the laser diode without changing the resultant shape of the laser beam. Neither protective lenses nor focusing optics necessarily provide an apparatus for obtaining a desired perimeter or spot shape. Accordingly, beam-shaping optics are not inherent in focusing optics or a protective lens.

[2] *See* August 2, 2006 Appeal Brief pp. 17-22 and March 5, 2007 Appeal Brief, p. 15, attached hereto as R-2 and R-3 respectively.

Because Lai fails to expressly or inherently disclose an optical arrangement for transforming a laser beam into a desired beam shape, Applicants' claims 1, 2, 8-10, 13-15 and 22 are not anticipated by Lai.

3. Conclusion

Applicants have shown that Claims 1, 2, 8-10, 13-15 and 22 are not anticipated under 35 USC 102(b) by Lai, and reversal of the rejection is respectfully requested.

B. Applicant's Claims Are Not Obvious Under 35 USC 103(a) in Light of U.S. Patent 6,267,779 Issued to Gerdes in View of U.S. Patent 5,653,706 Issued to Zavislan et al.

The Examiner argues that Applicant's claims 1-10, 13-30 and 32 are unpatentable over U.S. Patent 6,267,779 issued to Gerdes (hereinafter "Gerdes") in view of U.S. Patent 5,653,706 issued to Zavislan et al. (hereinafter "Zavislan").[3] The Examiner makes a number of arguments: that Zavislan is analogous art; that Gerdes and Zavislan do not teach away from Applicants' invention; that Gerdes and Zavislan inherently disclose elements of applicants' claims; and that Gerdes expressly teaches ultraviolet radiation and a variety of spot shapes. Applicants respectfully continue to disagree with the Examiner's arguments.

Principles of Law Relating to Obviousness & Inherency

A claim is *prima facie* obvious only if an analogous prior art reference (or references when combined) teaches or suggests all the claim limitations. MPEP §2142. According to the Supreme Court, in the recent case *KSR Int'l Co. v. Teleflex Inc.*, when combining references there must be "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new

[3] Gerdes and Zavislan are attached hereto as References R-4 and R-5 respectively.

invention does." 550 U.S. ___, 14, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385 (2007). Moreover, the Supreme Court instructs that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *Id.* at 12, 127 S.Ct. at 1739 (citing *United States v. Adams,* 383 U.S. 39, 51-52, 148 USPQ 479 (1966)).

In applying the *KSR* decision to a recent case, the Federal Circuit instructed that a prior art reference may be said to teach away from a combination or invention when a person of ordinary skill, upon reading of the reference, would be discouraged from following the path set out in the reference or would be led in a different direction from the path that was taken by the applicant. *In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1381, 83 USPQ2d 1746 (Fed. Cir. 2007) (quoting *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130 (Fed. Cir. 1994) and citing *KSR* at 12, 127 S.Ct. at 1739-40). "Additionally, a reference may teach away from a use when that use would render the result inoperable." *Id.* (citing *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354, 60 USPQ2d 1001 (Fed. Cir. 2001)).

Where a reference is alleged to inherently teach an element, the Federal Circuit has explained that the inherent characteristic must be a "necessary and inevitable" consequence of the disclosure in a prior art reference. *Schering* at 1378-80; *Continental Can* at 1268, 20 USPQ2d at 1749. It is not sufficient to show that the prior art would probably, or possibly, produce the undisclosed element. *Continental Can* at 1269, 20 USPQ2d at 1749; see also *MEHL/Biophile* at 1365, 52 USPQ2d at 1305 ("Occasional results are not inherent.").

1. Zavislan is not analogous art.

Applicants respectfully disagree with the Examiner that Zavislan is analogous art. While Zavislan teaches a single handheld laser device, it teaches one in an entirely different field that solves an unrelated problem, as detailed in Applicants' prior brief.[4] Zavislan's disclosure and Applicants' invention are in different fields of endeavor and, although both involve laser radiation, therapeutic lasers and surgical lasers cause dramatically different results on a patient's body and must therefore be designed considering different parameters and safety concerns. Accordingly, Zavislan is non-analogous art, and Applicants' claims 1-10, 13-30, and 32 are not obvious over Gerdes in view of Zavislan.

2. Zavislan teaches away from multiple wands.

Applicants respectfully disagree with the Examiner that, despite teaching away, Zavislan can be combined with Gerdes because Zavislan is merely cited for the teaching of mounting a laser within a probe. As detailed in Applicants' prior brief,[5] Zavislan teaches away from using multiple wands because it discloses a high power laser for ablative dermatology treatments, and multiple ablative wands cannot safely be used by hand: a practitioner can't see two places simultaneously to cut two places simultaneously. Because Zavislan teaches technology requiring different design parameters and considerations than those facing low-power therapeutic laser device developers, a person skilled in the art of therapeutic laser devices would be discouraged by the path set out in Zavislan. Accordingly, Applicants' claims 1-10, 13-30, and 32 are not obvious over Gerdes in view of Zavislan.

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[4] *See* March 5, 2007 Appeal Brief, pp. 16-18, 25-27 and 31-33.
[5] *See* March 5, 2007 Appeal Brief, pp. 18-20, 27-28 and 33-34.

3. Zavislan and Gerdes teach away from freely moving the probes.

Applicants respectfully disagree with the Examiner that the laser probes disclosed in Zavislan and Gerdes are capable of freely moving while emitting laser beams. Applicants further assert that Zavislan and Gerdes teach away from freely moving probes that emit laser beams.

First, neither Zavislan nor Gerdes inherently disclose that multiple handheld wands are capable of being freely movable while emitting laser beams. Zavislan's teachings do not necessarily or inevitably require free movement of its laser while it is operating. Rather, according to Zavislan, the laser is operated after the laser module is positioned over the treatment area. *See* Zavislan, col. 4, lines 55-60. Similarly, the laser probes in Gerdes also do not necessarily or inevitably permit free movement during radiation. Gerdes describes sophisticated software for controlling the operation of the therapeutic lasers so that they are only energized once the laser wands are placed in the proper position. *See* Gerdes, col. 12, lines 2-52. Moreover, Gerdes discloses an automatic positioning device that holds the laser wands so that their beams properly intersect. *See* Gerdes, col. 13, lines 22-35. Zavislan and Gerdes both expressly disclose how to operate their laser probes *without* achieving free movement during laser operation.

Second, combining the teachings of Zavislan and Gerdes to achieve Applicants' invention is not obvious or even sensible. Taking a high-power ablative laser as disclosed by Zavislan and combining it with multiple lasers intended to intersect as disclosed by Gerdes and then further adapting them to freely move while they are

emitting laser beams would be impractical, contrary to the express purposes of Gerdes and Zavislan, and highly dangerous. The fact that neither Gerdes nor Zavislan includes the interlocks described by the Examiner only further supports Applicants' position that the laser probes in Gerdes and Zavislan were never intended or even contemplated to be freely moved while emitting laser light.

Because both Gerdes and Zavislan do not inherently disclose, and rather teach away from, freely moving hand-held probes while they emit laser beams, Applicants' claims 1-10, 13-30, and 32 are not obvious over Gerdes in view of Zavislan.

4. Zavislan and Gerdes teach away from emitting two laser beams simultaneously and impinging two different parts of a patient's body.

Applicants respectfully disagree with the Examiner that Gerdes discloses laser probes capable of simultaneously impinging two different places on a patient. Gerdes does not inherently disclose simultaneously laser treating two different places, and both Gerdes and Zavislan teach away from it.

First, Gerdes does not inherently disclose that its laser beams are capable of impinging two different parts of a patient's body. Rather, simultaneously treating multiple areas of a patient is expressly discouraged rather than being a necessary or inevitable result of practicing Gerdes' teachings. Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersect in one area for the desired treatment of the patient. Moreover, Gerdes teaches significant safety measures to ensure its lasers are correctly intersecting prior to radiation and even discloses an apparatus for securing the laser modules in such a position. *See* Gerdes, col. 12, lines 2-52, and col. 13, lines 22-35.

Second, as explained above, Zavislan teaches an ablative laser device wherein the wand is visually positioned over a treatment area where microsurgery is desired, and it would be impractical, possibly even dangerous, to simultaneously treat multiple areas on the patient. A person of ordinary skill in the art would not consider Zavislan's teachings as appropriate for modifying Gerdes to achieve Applicants' claimed invention. Accordingly, Applicants' Claim 2 is not obvious over Gerdes in view of Zavislan.

5. Gerdes does not teach using ultraviolet laser light.

Applicants respectfully disagree with the Examiner that Gerdes teaches the use of ultraviolet light. As detailed in Applicants' prior brief,[6] ultraviolet light ranges from about 4 nm to less than 400 nm, just beyond violet in the visible spectrum of light. Gerdes only discloses aiming *visible* radiation having a wavelength of between approximately 400 nm and 700 nm. It is well known that ultraviolet light is not visible light. See, e.g., RANDOM HOUSE UNABRIDGED DICTIONARY 2051 (2d ed. 1993) (defining ultraviolet as "beyond the violet in the spectrum, corresponding to light having wavelengths shorter than 4000 angstrom units). Furthermore, Gerdes only discloses visible light. Therefore, Gerdes does not teach or suggest an ultraviolet wavelength, and Applicants' claims 16 and 29 are not obvious over Gerdes in view of Zavislan.

6. Gerdes does not teach various spot shapes.

Applicants respectfully continue to disagree with the Examiner that Gerdes teaches a variety of spot shapes. As detailed in Applicants' prior brief, [7] Gerdes only discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention." A linear spot

[6] *See* March 5, 2007 Appeal Brief, pp. 22-24 and 29-30.
[7] *See* March 5, 2007 Appeal Brief, pp. 24-25.

shape and plus-sign spot shape, however, are not "spread out." Therefore, Gerdes does not disclose or suggest a line or plus-sign spot shape, and Applicants' claims 17, 19, and 21 are not obvious over Gerdes in view of Zavislan.

7. Conclusion

Applicants have shown that Claims 1-10, 13-30, and 32 are not obvious under 35 USC 103(a) in light of Gerdes and Zavislan for one or more reasons explained above. Reversal of the rejections is respectfully requested.

II. Conclusion

Applicants believe they have shown that none of the Examiner's rejections in the pending application should be sustained. Applicants respectfully request that the Board reverse all the Examiner's rejections and allow the case to proceed to issuance.

Respectfully submitted,

Date: 4/17/2009

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Claims Appendix

1. A multi-probe device comprising:

   a) two or more laser energy sources, each generating one or more laser beams;

   b) two or more handheld probes from which the laser beams emit, wherein:

      i. each of the handheld probes houses one or more laser energy sources therewithin;

      ii. each of the handheld probes emits one or more laser beams, and each of the handheld probes is not connected to a support structure while being freely moved by a user's hand relative to the surface of the skin of a patient; and

   c) an optical arrangement attached to each handheld probe for receiving one or more laser beams and for transforming each of the laser beams into a desired spot shape.

2. A device according to claim 1 wherein at least two of the laser beams are emitted simultaneously and impinge two different parts of a patient 's body.

3. A device according to claim 1 further comprising one or more control circuits for independently controlling each of the generated laser beams.

4. A device according to claim 1 further comprising a control circuit for controlling the pulse repetition rate of each laser beam.

5. A device according to claim 4 wherein the pulse repetition rate of at least one of the laser beams is such that the laser light emitted is substantially continuous.

6. A device according to claim 4 further comprising a first laser beam having a first pulse repetition rate and a second laser beam having a second pulse repetition rate wherein the first pulse repetition rate and the second pulse repetition rate are different.

7. A device according to claim 4 further comprising a first laser beam having a first pulse repetition rate and a second laser beam having a second pulse repetition rate wherein the first pulse repetition rate and the second pulse repetition rate are the same.

8. A device according to claim 1 wherein each of the laser energy sources is less than one watt.

9. A device according to claim 1 wherein at least one of the laser energy sources is a semiconductor diode.

10. A device according to claim 1 further comprising a base.

13. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the visible range.

14. A device according to claim 13 wherein the wavelength of the laser beam is in the red range of the visible spectrum.

15. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the infrared range.

16. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the ultraviolet range.

17. A device according to claim 1 wherein at least one of the spot shapes is substantially linear.

18. A device according to claim 1 wherein at least one of the spot shapes is substantially circular.

19. A device according to claim 1 wherein at least one of the spot shapes is substantially in the shape of a plus-sign.

20. A device according to claim 1 wherein at least one of the spot shapes is substantially elliptical.

21. A device according to claim 1 further comprising a first laser beam having a first spot shape and a second laser beam having a second spot shape wherein the first spot shape is different from the second spot shape.

22. A device according to claim 1 further comprising a first laser beam and a second laser beam having the same spot shape.

23. A therapeutic laser device comprising:

a) a first semiconductor diode laser energy source generating a first laser beam and a second semiconductor diode laser energy source generating a second laser beam;

b) a first handheld probe from which the first laser beam emits, the first handheld probe having an interior cavity that houses the first semiconductor laser energy source therewithin and that is freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam;

c) an optical arrangement mounted in the interior cavity of the first handheld probe for receiving the first laser beam and for transforming the first laser beam into a desired spot shape;

d) a second handheld probe from which the second laser beam emits, the second handheld probe having an interior cavity that houses the second semiconductor laser energy source therewithin and that is freely moved by the user's hand relative to the surface of the skin of a patient and relative to the first handheld probe while emitting a laser beam;

e) an optical arrangement mounted in the interior cavity of the second handheld probe for receiving the second laser beam and for transforming the second laser beam into a desired spot shape; and

f) a control circuit for independently controlling each of the generated laser beams; and

g) wherein the first and second handheld probes are not connected to a support structure while being freely moved relative to the surface of the skin of a patient.

24. A device according to claim 23 further comprising a base.

25. A device according to claim 24 wherein the control circuit is housed in the base.

26. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the visible range.

27. A device according to claim 26 wherein the wavelength of the laser beam is in the red range of the visible spectrum.

28. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the infrared range.

29. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the ultraviolet range.

30. A multi-probe device comprising:

a) two or more laser energy sources housed in two or more handheld probes for generating two or more laser beams of only visible light wherein each beam of visible light is emitted at a different wavelength from the other beams of visible light;

b) wherein each of the handheld probes is retained in a hand of a user and freely moved relative to the surface of the skin of a patient; and

c) an optical arrangement attached to each handheld probe for receiving the laser beams and for transforming each of the laser beams into a desired spot shape.

32. A device according to claim 30 wherein the wavelengths of the laser beams are in the red range of the visible spectrum.

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Applicants: SHANKS, Steven C. and TUCEK, Kevin B.
Title of Invention: Multi-Probe Device
Filed: July 1, 2003
Serial Number: 10/612,504
Atty Docket No.: 206-038

Examiner: Henry M. Johnson, III
Art Unit: 3739

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8/2/06
Date

Sandra L. Etherton

Express Mail Number: ED 700 061 088 US

APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

A Notice of Appeal was filed May 2, 2006 which subsequently requires an appeal brief to be filed within two months. This Appeal Brief is submitted within three months of the Notice of Appeal and Applicants petition for a one-month extension. A charge form for the appeal fee of $250 and the extension fee of $60 accompanies this brief.

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Appendix R-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Applicants: SHANKS, Steven C. and TUCEK, Kevin B.
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APPEAL BRIEF

Table of Contents

VII. Argument

A. Lai Does Not Anticipate Applicants' Claims under 35 USC 102(b)

B. Applicants' Claims are Not Obvious Under 35 USC 103(a)

Cases Cited

In re Fulton, 391 F. 3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004)

In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983)

Hansgirg v. Kemmer, 40 USPQ 665 (CCPA 1939)

In re King, 231 USPQ 136 (Fed. Cir. 1986)

In re Oelrich and Divigard, 212 USPQ 323 (CCPA 1981)

In re Ratti, 123 USPQ 349 (CCPA 1959)

In re Rijckaert, 28 USPQ2nd 1955 (Fed. Cir. 1993)

In re Rouffet, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998)

MEHL/Biophile Int'l Corp. v. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)

Verdegaal Brothers, Inc. v. Union Oil Company of California, 2 USPQ2d 1051 (Fed. Cir. 1987)

List of References

R-1 Applicants' Specification and Drawings of U.S. Patent Application No. 10/612,504, as amended (referred to herein as the "Pending App.")

R-2 U.S. Patent 6,074,411 issued to Lai (referred to herein as "Lai")

R-3 U.S. Patent 6,267,779 issued to Gerdes (referred to herein as "Gerdes")

R-4 Office action dated November 10, 2005

Copies of the references above are included in the References Cited Appendix

Manual of Patent Examining Procedure, Eighth Edition, August 2001, Rev. 4 October 2005

MPEP §2112.02

MPEP §2142

MPEP §2143.01

MPEP §2146

I. Real Party in Interest

The real parties in interest are the inventors, Steven C. Shanks and Kevin B. Tucek.

Appellants note that, in the event a terminal disclaimer is required to avoid a double-patenting type obviousness rejection, upon a notice of allowance and assuming such terminal disclaimer is still required, Applicants will file a terminal disclaimer and an assignment fully complying with 37 CFR § 1.321 and 37 CFR § 3.73. In such case, the real parties in interest will include Erchonia Patent Holdings, LLC, owned in the majority by the inventors.

II. Related Appeals and Interferences

No appeals or interferences are pending which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal, however the following are, or were, copending patent applications or litigation related to the application on appeal:

Type	Application or Patent Number	How Related to Application on Appeal	Atty Docket Number
US Patent	6,605,079	this patent claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-001
US Patent	09/932,907 now U.S. Pat. No 6,746,473	this application claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-002
PCT Application	PCT/US2002/019359	PCT application, and national stage applications and issued patents therefrom, claim the benefit of the common priority application US Pat. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-021
CIP of related application	10/772,973	this application claims the benefit of common priority application U.S. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-024
CIP of related application	10/772,738	this patent application claims the benefit of common priority application U.S. Application No.	206-032

		09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	
judicial proceeding in Federal District Court of Colorado*	04-MK-1769 (CBS)	litigation alleging infringement of U.S. Pat. No 6,746,473 and invalidity thereof, et alia. U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-066
CIP of Patent Application on appeal	11/443980	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-071
DIV of Patent Application on appeal	11/431257	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-133

* A Markman hearing was held in Colorado District Court action 04-MK-1769 (CBS) to construe certain claims of U..S Patent No. 6,746,473, which claims the benefit of common priority application 09/932,907, now U.S. Pat. No. 6,746,473. That decision is attached in the Related Proceedings Appendix as Appendix RP-1. No other decisions have been rendered by a court or the Board in any proceeding identified under this section.

III. Status of the Claims

Claims 1-10, 13-30, and 32 of U.S. Patent Application No. 10/612,504 are pending and stand rejected twice and constitute the subject matter of this appeal. Claims 11-12, 31, 33 -34 have been cancelled. Claims 35-39 were withdrawn by the Examiner.

IV. Status of Amendments

Applicant proposed amendments subsequent to the final office action dated November 10, 2005. Those amendments were considered, but not entered, by the Examiner.

Claim amendments made in response to an office action dated June 3, 2005 were entered by the Examiner in an office action dated November 10, 2005. Those amended claims constitute the subject matter of this appeal and appear in the Claims Appendix as Appendix A.

V. Summary of Claimed Subject Matter

In U.S. Patent Application No. 10/612,504, the Applicants present a single laser device that enables a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. paragraphs [0005], [0006], [0007] and [0024] and Fig. 7. This is an improvement over prior art because earlier devices could not freely treat different areas of a patient at the same time.

The claimed device also enables a practitioner to personally and freely treat a patient using multiple laser beam emissions each with a specific spot shape, such as a line. Pending App. paragraphs [0018], lines 1-3. This has the advantage of enabling the practitioner to more precisely define the surface area the laser impinges upon. A copy of Applicants' specification, as amended, and drawings are enclosed for easy reference as Appendix R-1. The claims on appeal are listed in the Claims Appendix.

A. Independent Claim 1

Claim 1 defines a device (Pending App. paragraph [0015], line 1) having two or more handheld probes (Pending App. paragraph [0015], line 4). Each of the probes houses one or more laser energy sources (Pending App. paragraph [0016], lines 1-3) and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph 0017, lines 1-3). Each probe is moved freely by the user while the laser beams are being emitted (Pending App. paragraphs [0015] and [0024]; Fig. 7).

B. Independent Claim 23

Claim 23 generally defines the same device as claim 1, except that it specifies that the laser energy sources must be semiconductor laser diodes and adds a control circuit for controlling the laser beams. Specifically, Claim 23 covers a laser device (Pending App. paragraph [0015], line 1) having first and second handheld probes (Pending App. paragraph [0015], line 4). Each of the probes has a semiconductor diode (Pending App. paragraph [0022], lines 3-7) laser energy source (Pending App. paragraph [0016], lines 1-3), and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). There is a control circuit for independently controlling each of the laser beams (Pending App. paragraph [0020], lines 1-9). Each probe is freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

C. Independent Claim 30

Claim 30 generally defines the same device as claim 1 except that it specifies that each laser beam emits a different wavelength of visible light. Specifically, Claim 30 covers a device having two or more laser energy sources (Pending App. paragraph [0016], lines 1-3) housed in two or more handheld probes (Pending App. paragraph [0015], line 4). Each laser beam emits a visible wavelength (Pending App. paragraph [0022], lines 2-8) shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). Each probe can be moved freely by the user while the laser beams are being emitted (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

None of the claims on appeal recite means-plus-function limitations.

VI. Grounds of Rejection to be Reviewed on Appeal

A. **Are Claims 1, 2, 8-10, 13-15, 22, 30 and 32 unpatentable under 35 USC 102(b) as being anticipated by U.S. Patent 6,074,411 issued to Lai?**

B. **Are Claims 3-7, 16-22, and 23-29 unpatentable under 35 USC 103(a) as being obvious in light Lai in view of U.S. Patent 6,267,779 issued to Gerdes?**

C. **Are Claims 1-10, 13-14, 17, 18, 21, and 23-27 unpatentable as double-patenting claims 1-11 and 13 of U.S. Patent 6,746,473 issued to Shanks and Tucek??**

VII. Argument

A. Lai Does Not Anticipate Applicants' Claims under 35 USC 102(b)

Legal Standard for Anticipation

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers, Inc. v. Union Oil Company of California,* 2 USPQ2d 1051 (Fed. Cir. 1987). Under the principles of inherency, if the prior art in its normal and usual operation would necessarily perform the method claimed, then the method claimed will be considered to be anticipated. MPEP §2112.02. *See MEHL/Biophile Int'l Corp. v. Milgraum,* 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citing *In re King*, 231 USPQ 136, 138 (Fed. Cir. 1986)). However, the fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. MPEP §2112.02 (citing *In re Rijckaert, 28 USPQ2nd 1955, 1957 (Fed. Cir. 1993;. In re Oelrich and Divigard, 212 USPQ 323,326 (CCPA 1981) (citing Hansgirg v. Kemmer, 40 USPQ 665 (CCPA1939)).*

Applicants' burden is to prove that that Lai's device would not perform the claimed invention in its normal and usual operation. *See In re King* at 138.

1. Lai Does Not Anticipate Claims 1, 2, 8-10, 13-15, and 22 Because Lai Does Not Disclose Moving Probes While Emitting Laser Beams

Each of Applicants' claims 1, 2, 8-10, 13-15, and 22 claims handheld probes that "emit one or more laser beams ...while being freely moved by a user's hand..."[1]

Lai does not disclose however, that the probes emit one or more laser beams *while* being freely moved by a user's hand. Instead, Lai discloses how to *eliminate* having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a hands-free laser diode module during laser treatment. *See, e.g.* Lai column 3, lines 32-33 ("without holding said respective diode laser module by a person's hand"); Lai column 4, line 30 ("without holding by a person's hand").

The fact that a practitioner using the Lai device may move the probes while they emit laser light is not sufficient to establish the inherency of that result or characteristic. During normal and usual operation, a person operating Lai's device would not move the probes while they emit laser light. On the contrary, handholding the probes of Lai's device while they emit laser light would defeat the stated purpose of Lai's invention. Therefore, handheld probes that are freely moveable during laser operation are not inherently disclosed by Lai. Accordingly, claims 1, 2, 8-10, 13-15 and 22 are not anticipated by Lai.

[1] To forestall any confusion about the placement of the "support structure" limitation in claim 1 without a trailing comma and whether Applicants intended laser beams to be moved during treatment, Applicants note that clause (b)(ii) of claim 1 as amended in the RCE dated April 27, 2005, reads "each of the handheld probes emits one or more laser beams while being freely moved by a user's hand relative to the surface of the skin of the patient."

2. Lai Does Not Anticipate Claims 1, 2, 8-10, 13-15, and 22 Because Lai Does Not Disclose a Beam-Shaping Apparatus

Each of Applicants' claims 1, 2, 8-10, 13-15, and 22 claims "an optical arrangement for receiving one or more laser beams and for transforming each of the laser beams into a desired spot shape."

Lai does not expressly or inherently disclose, however, an optical arrangement to transform the beams into a desired spot shape. Instead, Lai discloses only focusing optics. *See* Lai column 2, lines 33-34. Focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent's skin. *See* Pending App. paragraph [0017]. Focus is defined in optics as "the clear and sharply defined condition of an image" and "the position of a viewed object or the adjustment of an optical device necessary to product a clear image." RANDOM HOUSE UNABRIDGED DICTIONARY 742 (2nd ed. 1987) (attached as Exhibit E-1). A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the resultant shape. That is, focusing optics are not inherent in beam shaping optical arrangements. For example, a linear beam has a linear shape, but may be in or out of focus:

linear beam spot in focus

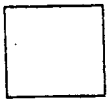
linear beam spot out of focus

Similarly a circular beam spot may be in or our of focus:

circular beam spot in focus

circular beam spot out of focus

Similarly a square beam spot may be in or our of focus:



square beam spot in focus

square beam spot out of focus

Focusing optics do not necessarily provide an apparatus for obtaining a desired spot shape. Therefore, Lai does not disclose, either expressly or inherently, an optical arrangement for transforming the beam shape, and claims 1, 2, 8-10, 13-15 and 22 are not anticipated by Lai.

3. Lai Does Not Anticipate Claims 1, 2, 8-10, 13-15, and 22 Because Lai Does Not Disclose a Spot Shape

Each of Applicants' claims 1, 2, 8-10, 13-15, and 22 claims "an optical arrangement for receiving one or more laser beams and for transforming each of the laser beams into a desired spot shape."

A spot shape is the result of a beam shape, as explained in Applicants' specification at paragraph [0017]. Lai does not disclose a beam shape, as admitted by the

Examiner on page 4 of the office action dated November 10, 2005: "Lai et al. is discussed above but does not disclose independent control of the lasers, ultraviolet wavelengths or beam shape." Instead, Lai discloses only how to focus a beam. However, focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent's skin as illustrated in the figures above, which are incorporated into this section by reference. *See also* Pending App. paragraph [0017]. Focus is defined in optics as "the clear and sharply defined condition of an image" and "the position of a viewed object or the adjustment of an optical device necessary to product a clear image." RANDOM HOUSE DICTIONARY AT 742. A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the underlying shape. That is, a spot shape is not inherent in focusing optics.

Lai does not disclose, either expressly or inherently, a spot shape. Therefore, claims 1, 2, 8-10, 13-15 and 22 are not anticipated by Lai.

4. Lai Does Not Anticipate Claims 30 and 32 Because Lai Does Not Disclose Hand-held Probes While Emitting Laser Beams

Each of Applicants' claims 30 and 32 claims "...handheld probes for generating two or more laser beams of only visible light ...wherein each of the handheld probes is retained in a hand of a user and freely moved relative to the surface of the skin of a patient."

Lai does not disclose that the probes emit one or more laser beams while being freely moved by a user's hand. Instead, Lai discloses how to eliminate having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other

tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a hands-free laser diode module during laser treatment. *See e.g.* Lai column 3, lines 32-33 ("without holding said respective diode laser module by a person's hand" Lai column 4, Line 30 ("without holding by person's hand").

The fact that a practitioner using the Lai device may move the probes while they emit laser light is not sufficient to establish the inherency of that result or characteristic. During normal and usual operation, a person operating Lai's device would not move the probes while they emit laser light. On the contrary, handholding the probes of Lai's device while they emit laser light would defeat the stated purpose of Lai's invention. Therefore, handheld probes that are freely moveable during laser application are not inherently disclosed by Lai. Accordingly, claims 30 and 32 are not anticipated by Lai.

5. Lai Does Not Anticipate Claims 30 and 32 Because Lai Does Not Disclose a Beam-Shaping Apparatus

Each of Applicants' claims 30 and 32 claims "an optical arrangement attached to each handheld probe for receiving the laser beams and for transforming each of the laser beams into a desired spot shape.

Again, Lai does not expressly or inherently disclose an optical arrangement to transform the beams into desired spot shape. Instead, Lai discloses only focusing optics. *See* Lai column 2, line 30. Focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent's skin. *See* Pending App. paragraph [0017]. Focus is defined in optics

as "the clear and sharply defined condition of an image" and "the position of a viewed object or the adjustment of an optical device necessary to product a clear image." RANDOM HOUSE DICTIONARY AT 742. A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the resultant shape. That is, an optical arrangement for transforming the beam shape is not inherent in focusing optics.

Lai does not disclose, either expressly or inherently, an optical arrangement for transforming the beam shape. Therefore, claims 30 and 32 are not anticipated by Lai.

6. Lai Does Not Anticipate Claims 30 and 32 Because Lai Does Not Disclose a Spot Shape

Each of Applicants' claims 30 and 32 claims "an optical arrangement attached to each handheld probe for receiving the laser beams and for transforming each of the laser beams into a desired spot shape."

Again, a spot shape is the result of a beam shape, as explained in Applicants' specification. Pending App. at paragraph [0017]. Lai does not disclose a beam shape, however, as admitted by the examiner on page 4 of the office action dated November 10, 2005. Examiner's quote, *supra* p. 19. Instead, Lai discloses only how to focus a beam. Focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent's skin as illustrated by the figures above, which are incorporated into this section by reference. *See also* Applicants' specification at paragraph [0017]. Focus is defined in optics as "the clear and sharply defined condition of an image" and "the position of a viewed object or the adjustment of an optical device necessary to product a clear image."

RANDOM HOUSE DICTIONARY AT 742. A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the underlying shape. That is, a spot shape is not inherent in focusing optics.

Lai does not disclose, either expressly or inherently, a spot shape. Therefore, claims 30 and 32 are not anticipated by Lai.

Conclusion

Applicants have shown that Claims 1, 2, 8-10, 13-15, 22, 30 and 32 are not anticipated under 35 USC 102(b) by Lai, and reversal of the rejection is respectfully requested.

B. Applicants' Claims are Not Obvious Under 35 USC 103(a)

Legal Standard for Obviousness

To establish *a prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference or combine the teachings. MPEP §2142; *In re Rouffet*, 149 F.3d 1350, 1356, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998); *In re Geiger* 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). The references must be considered as a whole, and there must be something in the prior art as a whole to suggest the desirability of the combination. MPEP §2142; *In re Fulton*, 391 F 3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004). Moreover, it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125,1127 (Fed. Cir. 1984). *See also* MPEP §2146; *In re Grasselli, 218 USPQ 769, 779 (Fed. Cir. 1983)*; *In re Ratti*, 123 USPQ 349, 352, CCPA 1959.

1. Claims 3-7 and 16-22 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Hand-held Probes

Each of Applicants' claims 3-7 and 16-22 teaches probes that are handheld and freely moved by the user's hand. Although Gerdes teaches hand-held wands, Lai expressly teaches away from hand-held wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

The problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands. Lai accomplishes this by providing laser diode modules that attach onto a patient's body during treatment using a self-adhesive holder. *See* Lai

column 1, lines 38-39. Lai explains that "[i]t has an adhesive surface and allows to attach a diode laser module onto an acupuncture point of a body part *free of hand-holding*." Lai column 1, lines 46-48 (emphasis added). "Such holding mechanism is particularly advantageous since it *eliminates the need for hand holding the laser module* and allows the therapist to perform other tasks." Lai column 2, lines 29-31 (emphasis added). Nowhere in Lai's disclosure is there any suggestion that handheld wands are desirable. Instead Lai expresses the opposite: the desire is *not* to have hand-held wands. Therefore, Lai expressly teaches against probes that are handheld. Because it is improper to combine references when one teaches away from the combination, Lai and Gerdes should not be combined, and no *prima facie* case of obviousness has been made.

2. Claims 3-7 and 16-22 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Moving Probes While Emitting Laser Beams

Each of Applicants' claims 3-7 and 16-22 teaches handheld probes that "emit one or more laser beams ...while being freely moved by a user's hand..."[2] Lai expressly teaches away from moving the probes while laser beams are being emitted. Again, is well settled that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

The problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands while they are emitting laser beams. Lai explains that:

[2] To forestall any confusion about the placement of the "support structure" limitation in claim 1 without a trailing comma and whether Applicants intended laser beams to be moved during treatment, Applicants note that clause (b)(ii) of claim 1 as amended in the RCE dated April 27, 2005, reads "each of the handheld probes emits one or more laser beams while being freely moved by a user's hand relative to the surface of the skin of the patient."

> [S]timulating five to ten acupuncture points are [sic] common and each takes typically five to thirty minutes. Thus, a therapist needs to point the laser beam to one acupuncture point then another for a long time. Obviously, using these devices is inconvenient and is time consuming.

Lai at column 1, lines 27-31. Lai goes on to teach how to *eliminate* having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a hands-free laser diode module during laser treatment. *See e.g.* Lai column 3, lines 32-33 ("without holding said respective diode laser module by a person's hand"; Lai column 4, line 30 ("without holding by a person's hand). To make Lai's device with hand-held lasers would defeat the purpose of Lai's invention and lead to a device that is inoperative under the basic principles under which Lai is designed to operate. Therefore, Lai expressly teaches against probes that are hand-held while emitting laser beams.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, Lai and Gerdes cannot be combined, and no *prima facie* case of obviousness has been made.

3. Claims 3-7 and 16-22 are Not Obvious in Light of Lai and Gerdes Because the Prior Art Teaches Against Freely Moving the Probes

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 3-7 and 16-22 teach handheld probes that "emit one or more laser beams ...while being freely moved by a user's hand

relative to the surface of the skin of a patient." Gerdes and Lai each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. *See* Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically, for the laser beams to intersect, the wands must be treating substantially the same area of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Lai teaches the use of a self-adhesive holder for each of the diode lasers to attach onto a patient's body. Lai column 1, lines 38-40. The self-adhesive holder is configured to securely hold the diode laser module and to maintain the laser beam at the acupuncture point. Lai column 2, lines 26-31. It would render Lai inoperable to modify it such that the laser modules moved freely because then they would not be maintained at the acupuncture point.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Lai and Gerdes cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

4. Claim 16 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests Using Ultraviolet Laser Light

Applicants' claim 16 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Neither Lai nor Gerdes disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Lai discloses that the wavelength of the diode laser is selected to have a desirable penetration depth for effectively stimulating an acupuncture point. Lai column 2, lines 43-45. Any wavelength ranged from 500 nm to 1500 nm may be chosen for a variety of acupuncture treatments. Lai column 2, lines 49-51. The range of ultraviolet wavelengths is generally defined as less than 400 nm. Lai does not disclose a wavelength less than 500, and therefore Lai does not disclose ultraviolet wavelengths. The Examiner admits this on page 4 of the final office action dated November 10, 2005 : "Lai et al. is discussed above but does not disclose independent control of the lasers, ultraviolet wavelengths or beam shape." Further, Lai does not indicate that ultraviolet may be used to stimulate an acupuncture point. Therefore, Lai does not suggest using an ultraviolet wavelength.

Gerdes discloses exposing tissue to converging beams of treatment (infrared) radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength less than 400 nm.

The Examiner alleges on page 5 of the final office action that Gerdes discloses 400 nm of ultraviolet light at column 9, line 38. Gerdes actually refers to

visible light at 400 nm, however. Specifically, the Gerdes cite reads in its entirety:

> Additionally, each of the ***visible*** laser radiation sources 170 is also configured to emit radiation having a wavelength preferably between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes at column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light. Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Lai suggests the use of ultraviolet wavelengths, neither Lai nor Gerdes suggests using an ultraviolet wavelength. Lacking any suggestion or motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

5. Claim 17 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests a Linear Spot Shape

Applicants' claim 17 requires one of the spot shapes to be substantially linear. Lai does not disclose any beam shape, as the examiner admits on page 4 of the final office action dated November 10, 2005. Examiner's quote, *supra* p. 27. Moreover, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention," a line is not a "spread-out" spot shape. Instead, a linear spot shape is the antithesis of "spread-out." *See* Gerdes column 9, lines 45-49. Lacking any suggestion or motivation of a linear beam shape, no *prima facie* case of obviousness has been made.

6. Claim 19 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests a Plus-Sign Spot Shape

Applicants' claim 19 requires one of the spot shapes to be in the shape of a plus sign. Again, Lai does not disclose any beam shape, as the examiner admits on page 4 of the final office action dated November 10, 2005. Examiner's quote, *supra* p. 27. Also again, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention," a plus sign is not a "spread-out" spot shape. Gerdes at column 9, lines 46-49. Lacking any suggestion or motivation of a plus-sign spot shape, no *prima facie* case of obviousness has been made.

7. Claim 21 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests Different Spot Shapes

Applicants' claim 21 requires the spot shape of a first laser beam to be different from a spot shape of a second laser beam; that is, the first and second beam shapes are different. Again, Lai does not disclose any beam shape, as the examiner admits on page 4 of the final office action dated November 10, 2005. *Id.* While Gerdes discloses that a "wide variety" of "spread-out" beam shapes can be used, Gerdes not indicate that the beam shapes emitted form the radiation sources can be different from each other. Lacking any suggestion or motivation of a linear beam shape, no *prima facie* case of obviousness has been made.

8. Claims 23-29 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Handheld Probes

Each of Applicants' claims 23-29 teaches probes that are handheld and freely moved by the user's hand. As explained in section VII (B)(1) above, however, the problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands. Lai accomplishes this by providing laser diode modules that attach onto a patient's body during treatment using a self-adhesive holder. *See* Lai column 1, lines 38-39. Lai explains that "[i]t has an adhesive surface and allows to attach a diode laser module onto an acupuncture point of a body part *free of hand-holding*." Lai column 1, lines 46-48 (emphasis added). "The holding mechanism is particularly advantageous since it *eliminates the need for hand holding the laser module* and allows the therapist to perform other tasks. Lai column 2, lines 29-31, emphasis added. Therefore, Lai expressly teaches against probes that are hand-held.

Because it is improper to combine references when one reference teaches away from the combination, Lai and Gerdes cannot be combined, and no *prima facie* case of obviousness has been made.

9. Claims 23-29 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Moving Probes While Emitting Laser Beams

Each of Applicants' claims 23-29 teaches a first handheld probe "from which the first laser beam emits, the first handheld probe ... freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam."

As explained in section VII (B)(2) above, the problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands while they are emitting laser beams. Lai explains that:

> [S]timulating five to ten acupuncture points are [sic] common and each takes typically five to thirty minutes. Thus, a therapist needs to point the laser beam to one acupuncture point then another for a long time. Obviously, using these devices is inconvenient and is time consuming.

Lai at column 1, lines 27-31. Lai goes on to teach the laser therapy device art how to eliminate having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a laser diode module "without holding said respective diode laser module by a person's hand." *See* Lai column 3, lines 32-33; Lai column 4, lines 30. To make Lai's device with hand-held lasers would defeat the purpose of Lai's invention, and lead to a device that is inoperative under the basic principles under which Lai is designed to operate. Therefore, Lai expressly teaches against probes that are hand-held while emitting laser beams.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, Lai and Gerdes cannot be combined, and no *prima facie* case of obviousness has been made.

10. Claims 23-29 are Not Obvious in Light of Lai and Gerdes Because the Prior Art Teaches Against Freely Moving the Probes

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App.

Paragraphs [0006] and [0007]. Each of Applicants' claims 23-29 teach first and second handheld probes that are "freely moved by the user's hand relative to the surface of the skin of a patient while emitting the [first, second] laser beam." Gerdes and Lai each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. *See* Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically, for the laser beams to intersect, the wands must be treating substantially the same areas of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time, because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Lai teaches the use of a self-adhesive holder for each of the diode lasers to attach onto a patient's body. Lai column 1, lines 38-40. The self-adhesive holder is configured to securely hold the diode laser module and to maintain the laser beam at the acupuncture point. Lai column 2, lines 26-31. It would render Lai inoperable to modify it such that the laser modules moved freely because then they would not be maintained at the acupuncture point.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose and because in this case, both prior art references teach away from moving the probes freely, Lai and Gerdes cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

11. Claim 29 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests Using Ultraviolet Laser Light

Applicants' claim 29 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Neither Lai nor Gerdes disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Lai discloses that the wavelength of the diode laser is selected to have a desirable penetration depth for effectively stimulating an acupuncture point. Lai column 2, lines 43-45. Any wavelength ranged from 500 nm to 1500 nm may be chosen for a variety of acupuncture treatments. Lai column 2, lines 49-51. The range of ultraviolet wavelengths is generally defined as less than 400 nm. Lai does not disclose a wavelength less than 500, and therefore Lai does not disclose ultraviolet wavelengths, as the examiner admits on page 4 of the final office action dated November 10, 2005. Examiner's quote, *supra* p. 27. Further, Lai does not indicate that ultraviolet wavelengths may be used to stimulate an acupuncture point. Therefore, Lai does not suggest an ultraviolet wavelength.

Gerdes discloses exposing tissue to converging beams of treatment (infrared) radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength less than 400 nm.

The Examiner alleges on page 5 of the final office action that Gerdes discloses 400 nm of ultraviolet light at column 9, line 38. Gerdes actually refers to *visible* light at 400 nm however. Specifically, the Gerdes cite reads in its entirety:

> Additionally, each of the ***visible*** laser radiation sources 170 is also configured to emit radiation having a wavelength preferably

> between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light. Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Lai suggests the use of ultraviolet wavelengths, neither Lai nor Gerdes suggests using an ultraviolet wavelength. Lacking any suggestion or motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

Conclusion

For one or more reasons above, Applicants have shown that Claims 3-7, 16-22, and 23-29 are not obvious under 35 USC 103(a) in light of Lai and Gerdes. Reversal of the rejections is respectfully requested.

C. Claims 1-10, 13-14, 17, 18, 21, and 23-27 Cannot be Actually Rejected for Double-Patenting Because Claims Are Not Yet Otherwise Allowable

The Examiner has twice actually rejected claims 1-10, 13-14, 17, 18, 21, and 23-27 for being obvious under the non-statutory (judicially-created doctrine of) double patenting as being unpatentable over claims 1-11 and 13 of U.S. Patent 6,746,473 issued to Shanks and Tucek. However, none of these claims has yet been allowed, and therefore no actual double-patenting can be determined. Heretofore Applicant has stated that upon a notice of allowance, and assuming such terminal disclaimer is still required, Applicants will file a terminal disclaimer and an assignment fully complying with 37 CFR § 1.321 and 37 CFR § 3.73.

Applicants have shown that Claims 1-10, 13-14, 17, 18, 21, and 23-27 cannot be actually rejected for double-patenting and reversal of the rejection is respectfully requested.

VIII. Conclusion

Applicants believe they have shown that none of the Examiner's rejections in the pending application should be sustained. Applicants respectfully request that the Board reverse all the Examiner's rejections and allow the case to proceed to issuance.

Respectfully submitted,

Date: 8/2/06

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Claims Appendix

1. A multi-probe device comprising:

a) two or more laser energy sources, each generating one or more laser beams;

b) two or more handheld probes from which the laser beams emit, wherein:

i. each of the handheld probes houses one or more laser energy sources therewithin;

ii. each of the handheld probes emits one or more laser beams, and each of the handheld probes is not connected to a support structure while being freely moved by a user's hand relative to the surface of the skin of a patient; and

c) an optical arrangement attached to each handheld probe for receiving one or more laser beams and for transforming each of the laser beams into a desired spot shape.

2. A device according to claim 1 wherein at least two of the laser beams are emitted simultaneously and impinge two different parts of a patient 's body.

3. A device according to claim 1 further comprising one or more control circuits for independently controlling each of the generated laser beams.

4. A device according to claim 1 further comprising a control circuit for controlling the pulse repetition rate of each laser beam.

5. A device according to claim 4 wherein the pulse repetition rate of at least one of the laser beams is such that the laser light emitted is substantially continuous.

6. A device according to claim 4 further comprising a first laser beam having a first pulse repetition rate and a second laser beam having a second pulse repetition rate wherein the first pulse repetition rate and the second pulse repetition rate are different.

7. A device according to claim 4 further comprising a first laser beam having a first pulse repetition rate and a second laser beam having a second pulse repetition rate wherein the first pulse repetition rate and the second pulse repetition rate are the same.

8. A device according to claim 1 wherein each of the laser energy sources is less than one watt.

9. A device according to claim 1 wherein at least one of the laser energy sources is a semiconductor diode.

10. A device according to claim 1 further comprising a base.

13. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the visible range.

14. A device according to claim 13 wherein the wavelength of the laser beam is in the red range of the visible spectrum.

15. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the infrared range.

16. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the ultraviolet range.

17. A device according to claim 1 wherein at least one of the spot shapes is substantially linear.

18. A device according to claim 1 wherein at least one of the spot shapes is substantially circular.

19. A device according to claim 1 wherein at least one of the spot shapes is substantially in the shape of a plus-sign.

20. A device according to claim 1 wherein at least one of the spot shapes is substantially elliptical.

21. A device according to claim 1 further comprising a first laser beam having a first spot shape and a second laser beam having a second spot shape wherein the first spot shape is different from the second spot shape.

22. A device according to claim 1 further comprising a first laser beam and a second laser beam having the same spot shape.

23. A therapeutic laser device comprising:

a) a first semiconductor diode laser energy source generating a first laser beam and a second semiconductor diode laser energy source generating a second laser beam;

b) a first handheld probe from which the first laser beam emits, the first handheld probe having an interior cavity that houses the first semiconductor laser energy source therewithin and that is freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam;

c) an optical arrangement mounted in the interior cavity of the first handheld probe for receiving the first laser beam and for transforming the first laser beam into a desired spot shape;

d) a second handheld probe from which the second laser beam emits, the second handheld probe having an interior cavity that houses the second semiconductor laser energy source therewithin and that is freely moved by the user's hand relative to the surface of the skin of a patient and relative to the first handheld probe while emitting a laser beam;

e) an optical arrangement mounted in the interior cavity of the second handheld probe for receiving the second laser beam and for transforming the second laser beam into a desired spot shape; and

f) a control circuit for independently controlling each of the generated laser beams; and

g) wherein the first and second handheld probes are not connected to a support structure while being freely moved relative to the surface of the skin of a patient.

24. A device according to claim 23 further comprising a base.

25. A device according to claim 24 wherein the control circuit is housed in the base.

26. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the visible range.

27. A device according to claim 26 wherein the wavelength of the laser beam is in the red range of the visible spectrum.

28. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the infrared range.

29. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the ultraviolet range.

30. A multi-probe device comprising:

a) two or more laser energy sources housed in two or more handheld probes for generating two or more laser beams of only visible light wherein each beam of visible light is emitted at a different wavelength from the other beams of visible light;

b) wherein each of the handheld probes is retained in a hand of a user and freely moved relative to the surface of the skin of a patient; and

c) an optical arrangement attached to each handheld probe for receiving the laser beams and for transforming each of the laser beams into a desired spot shape.

32. A device according to claim 30 wherein the wavelengths of the laser beams are in the red range of the visible spectrum.

Evidence Appendix

Appendix E-1 Random House Unabridged Dictionary 2nd ed., 1987, definition of "focus," meanings 3c and 3d

Related Proceedings Appendix

Appendix RP-1 – Order Construing Patent Claim Terms of US Patent 6,746,473.

References Cited Appendix

R-1 Applicants' Specification of U.S. Patent Application No. 10/612,504, as amended, and Drawings (referred to herein as the "Pending App.")

R-2 U.S. Patent 6,074,411 issued to Lai (referred to herein as "Lai")

R-3 U.S. Patent 6,267,779 issued to Gerdes (referred to herein as "Gerdes")

R-4 Office action dated November 10, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Applicants: SHANKS, Steven C. and TUCEK, Kevin B.
Title of Invention: Multi-Probe Device
Filed: July 1, 2003
Serial Number: 10/612,504
Atty Docket No.: 206-038

Examiner: Henry M. Johnson, III
Art Unit: 3739

CERTIFICATE OF EXPRESS MAILING

I hereby certify that the following correspondence is being deposited with the United States Postal Service as EXPRESS MAIL, postage paid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

3/5/07
Date

Sandra L. Emerton

Express Mail Number: EQ 984 544 281 US

SUPPLEMENTAL APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

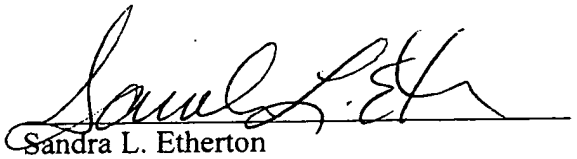
Dear Sir:

A Notice of Appeal/Request for Reinstatement of Appeal was filed January 29, 2007 which subsequently requires an appeal brief to be filed within two months. This Appeal Brief is timely submitted within two months of the Request for Reinstatement of Appeal. Applicants believe no fees are due.

The following documents are enclosed:

- Supplemental Appeal brief (35 sheets)
- Claims Appendix (6 sheets)
- Appendix E-1 (4 sheets including cover)
- Appendix RP (15 sheets including cover)
- Appendix R-1 (18 sheets including cover)

- Appendix R-2 (7 sheets)
- Appendix R-3 (19 sheets)
- Appendix R-4 (8 sheets)
- Appendix R-5 (46 sheets)
- Appendix R-6 (16 sheets)



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Applicants: SHANKS, Steven C. and TUCEK, Kevin B.
Title of Invention: Multi-Probe Device
Filed: July 1, 2003
Serial Number: 10/612,504 **Examiner**: Henry M. Johnson, III
Atty Docket No.: 206-038 **Art Unit:** 3739

SUPPLEMENTAL APPEAL BRIEF

Table of Contents

VII. Argument

Cases Cited

In re Fulton, 391 F. 3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004)

In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987)

In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966)

In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983)

Hansgirg v. Kemmer, 40 USPQ 665 (CCPA 1939)

In re King, 231 USPQ 136 (Fed. Cir. 1986)

In re Oelrich and Divigard, 212 USPQ 323 (CCPA 1981)

In re Oeticker, 977, F.2d 1443, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992)

In re Ratti, 123 USPQ 349 (CCPA 1959)

In re Rijckaert, 28 USPQ2nd 1955 (Fed. Cir. 1993)

In re Rouffet, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998)

MEHL/Biophile Int'l Corp. v. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)

Verdegaal Brothers, Inc. v. Union Oil Company of California, 2 USPQ2d 1051 (Fed. Cir. 1987)

List of References

R-1 Applicants' Specification and Drawings of U.S. Patent Application No. 10/612,504, as amended (referred to herein as the "Pending App.")

R-2 U.S. Patent 6,074,411 issued to Lai (referred to herein as "Lai")

R-3 U.S. Patent 6,267,779 issued to Gerdes (referred to herein as "Gerdes")

R-4 Office action dated November 10, 2005

R-5 Appeal Brief dated August 2, 2006

R-6 U.S. patent 5,653,706 issued to Zavislan (referred to herein as "Zavislan")

Copies of the references above are included in the References Cited Appendix

Manual of Patent Examining Procedure, Eighth Edition, August 2001, Rev. 4 October 2005

MPEP §2112.02

MPEP §2141.01(a)

MPEP §2142

MPEP §2143.01

MPEP §2146

I. Real Party in Interest

The real parties in interest are the inventors, Steven C. Shanks and Kevin B. Tucek.

Appellants note that, in the event a terminal disclaimer is required to avoid a double-patenting type obviousness rejection, upon a notice of allowance and assuming such terminal disclaimer is still required, Applicants will file a terminal disclaimer and an assignment fully complying with 37 CFR § 1.321 and 37 CFR § 3.73. In such case, the real parties in interest will now include Therapy Products, Inc. dba Erchonia Medical (formed as a result of the merger between Therapy Products, Inc. and Erchonia Medical, Inc), owned in the majority by the inventors.

II. Related Appeals and Interferences

No appeals or interferences are pending which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal, however the following are, or were, copending patent applications or litigation related to the application on appeal:

Type	Application or Patent Number	How Related to Application on Appeal	Atty Docket Number
US Patent	6,605,079	this patent claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-001
US Patent	09/932,907 now U.S. Pat. No 6,746,473	this application claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-002
PCT Application	PCT/US2002/019359	PCT application, and national stage applications and issued patents therefrom, claim the benefit of the common priority application US Pat. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-021
CIP of related application	10/772,973	this application claims the benefit of common priority application U.S. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-024
CIP of related application	10/772,738	this patent application claims the benefit of common priority application U.S. Application No.	206-032

		09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	
judicial proceeding in Federal District Court of Colorado*	04-MK-1769 (CBS)	litigation alleging infringement of U.S. Pat. No 6,746,473 and invalidity thereof, et alia. U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-066
CIP of Patent Application on appeal	11/443980	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-071
DIV of Patent Application on appeal	11/431257	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-133

* A Markman hearing was held in Colorado District Court action 04-MK-1769 (CBS) to construe certain claims of U..S Patent No. 6,746,473, which claims the benefit of common priority application 09/932,907, now U.S. Pat. No. 6,746,473. That decision is attached in the Related Proceedings Appendix as Appendix RP-1. No other decisions have been rendered by a court or the Board in any proceeding identified under this section.

III. Status of the Claims

Claims 1-10, 13-30, and 32 of U.S. Patent Application No. 10/612,504 are pending and stand rejected twice and constitute the subject matter of this appeal. Claims 11-12, 31, 33 -34 have been cancelled. Claims 35-39 were withdrawn by the Examiner.

IV. Status of Amendments

Applicants proposed amendments subsequent to the final office action dated November 10, 2005. Those amendments were considered, but not entered, by the Examiner.

Claim amendments made in response to an office action dated June 3, 2005 were entered by the Examiner in an office action dated November 10, 2005. Those amended claims constitute the subject matter of this appeal and appear in the Claims Appendix.

V. Summary of Claimed Subject Matter

In U.S. Patent Application No. 10/612,504, the Applicants present a single laser device that enables a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. paragraphs [0005], [0006], [0007] and [0024] and Fig. 7. This is an improvement over prior art because earlier devices could not freely treat different areas of a patient at the same time.

The claimed device also enables a practitioner to personally and freely treat a patient using multiple laser beam emissions each with a specific spot shape, such as a line. Pending App. paragraphs [0018], lines 1-3. This has the advantage of enabling the practitioner to more precisely define the surface area the laser impinges upon. A copy of Applicants' specification, as amended, and drawings are enclosed for easy reference as Appendix R-1. The claims on appeal are listed in the Claims Appendix.

A. Independent Claim 1

Claim 1 defines a device (Pending App. paragraph [0015], line 1) having two or more handheld probes (Pending App. paragraph [0015], line 4). Each of the probes houses one or more laser energy sources (Pending App. paragraph [0016], lines 1-3) and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph 0017, lines 1-3). Each probe is moved freely by the user while the laser beams are being emitted (Pending App. paragraphs [0015] and [0024]; Fig. 7).

B. Independent Claim 23

Claim 23 generally defines the same device as claim 1, except that it specifies that the laser energy sources must be semiconductor laser diodes and adds a control circuit for controlling the laser beams. Specifically, Claim 23 covers a laser device (Pending App. paragraph [0015], line 1) having first and second handheld probes (Pending App. paragraph [0015], line 4). Each of the probes has a semiconductor diode (Pending App. paragraph [0022], lines 3-7) laser energy source (Pending App. paragraph [0016], lines 1-3), and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). There is a control circuit for independently controlling each of the laser beams (Pending App. paragraph [0020], lines 1-9). Each probe is freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

C. Independent Claim 30

Claim 30 generally defines the same device as claim 1 except that it specifies that each laser beam emits a different wavelength of visible light. Specifically, Claim 30 covers a device having two or more laser energy sources (Pending App. paragraph [0016], lines 1-3) housed in two or more handheld probes (Pending App. paragraph [0015], line 4). Each laser beam emits a visible wavelength (Pending App. paragraph [0022], lines 2-8) shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). Each probe can be moved freely by the user while the laser beams are being emitted (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

None of the claims on appeal recite means-plus-function limitations.

VI. Grounds of Rejection to be Reviewed on Appeal

A. **Are Claims 1, 2, 8-10, 13-15, 22, 30 and 32 unpatentable under 35 USC 102(b) as being anticipated by U.S. Patent 6,074,411 issued to Lai?**

B. **Are Claims 3-7, 16-22, and 23-29 unpatentable under 35 USC 103(a) as being obvious in light U.S. Patent 6,074,411 issued to Lai in view of U.S. Patent 6,267,779 issued to Gerdes?**

C. **Are Claims 1-10, 13-14, 17, 18, 21, and 23-27 unpatentable as double-patenting claims 1-11 and 13 of U.S. Patent 6,746,473 issued to Shanks and Tucek?**

D. **Are Claims 1-10, 13-30, and 32 unpatentable under 35 USC 103(a) as being obvious in light of U.S. Patent 6,267,779 issued to Gerdes in view of U.S. Patent 5,653,706 issued to Zavislan et al?**

VII. Argument

A. Lai Does Not Anticipate Applicants' Claims under 35 USC 102(b).

Appellants incorporate by reference their arguments presented in section VII.A. at pp. 15-22 of their original Appeal Brief, filed August 2, 2006 and attached hereto as Appendix R-5.

B. Applicants' Claims are Not Obvious Under 35 USC 103(a) in light of U.S. Patent 6,074,411 issued to Lai in view of U.S. Patent 6,267,779 issued to Gerdes.

Appellants incorporate by reference their arguments presented in section VII.B. at pp. 16-34 of their original Appeal Brief, filed August 2, 2006 and attached hereto as Appendix R-5.

C. Claims 1-10, 13-14, 17, 18, 21, and 23-27 Cannot be Actually Rejected for Double-Patenting Because Claims Are Not Yet Otherwise Allowable.

Appellants incorporate by reference their arguments presented in section VII.C. at p.35 of their original Appeal Brief, filed August 2, 2006 and attached hereto as Appendix R-5.

D. Applicant's Claims are Not Obvious Under 35 USC 103(a) in light of U.S. Patent 6,267,779 issued to Gerdes in view of U.S. Patent 5,653,706 issued to Zavislan et al.

Legal Standard for Obviousness

In order to determine whether an invention is obvious in light of prior art, the Patent Office should make several basic factual inquiries, including the scope and content of the prior art. *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). The scope of the prior art should include only analogous prior art. MPEP §2141.01(a). In general, in order for a reference to be considered analogous prior art, the reference must either be in

the field of applicant's endeavor or, if not, be reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oeticker*, 977 F.2d 1443, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). Moreover, it is also necessary that a person of ordinary skill, seeking to solve a particular problem, would reasonably be expected or motivated to look to the allegedly analogous technology. *Id.*, 24 USPQ2d at 1446.

In addition to limiting prior art to only analogous art, to establish *a prima facie* case of obviousness, there also must be some suggestion or motivation to modify the reference or combine the teachings. MPEP §2142; *In re Rouffet*, 149 F.3d 1350, 1356, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998); *In re Geiger*, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). The references must be considered as a whole, and there must be something in the prior art as a whole to suggest the desirability of the combination. MPEP §2142; *In re Fulton*, 391 F 3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004). Moreover, it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125,1127 (Fed. Cir. 1984). *See also* MPEP §2146; *In re Grasselli, 218 USPQ 769, 779 (Fed. Cir. 1983)*; *In re Ratti*, 123 USPQ 349, 352, CCPA 1959.

1. Claims 1-10 and 13-22 are not obvious in light of Gerdes and Zavislan because Zavislan is non-analogous art.

Each of Applicants' claims 1-10 and 13-22 are directed at low-power therapeutic handheld laser probes that are freely moved by a user's hands for healing purposes. While Zavislan teaches a single handheld laser device, it teaches one in an entirely different field and solving an unrelated problem. It is well-settled law that it is improper to consider a reference that is non-analogous. *In re Oeticker*, 24 USPQ2d at 1446.

Applicant's invention is a handheld multi-probe non-ablative laser device for wound healing, edema reduction, pain relief, inflammation reduction, and other similar applications. Pending App. Paragraph [0003], lines 2-6. It uses low-level laser energy and causes no immediate detectable temperature rise and no macroscopically visible changes in tissue structure. Pending App. Paragraph [0004], lines 2-4. The treated and surrounding tissue is neither heated nor damaged. *Id.* Additionally, because no damage occurs where the laser beam is applied, more than one laser can be applied simultaneously for faster and improved therapy. Pending App. Paragraph [0005], lines 1-6.

Zavislan discloses a high-power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device uses thermolysis (from thermo- meaning heat and -lysis meaning break down), which is defined as a decomposition or dissociation of chemical compounds by use of heat. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 30-35. A laser treatment with the device disclosed in Zavislan necessarily causes a rise in temperature and changes in tissue structure to accomplish necrosis and cauterization. *Id*. In addition, particular attention to visualizing where the laser beam is applied is critical according to Zavislan so that the operator does not damage areas where no treatment is desired. Zavislan, column 2, lines 16-18.

Because therapeutic lasers and surgical lasers result in dramatically different results on a patient's body, they must be designed considering different parameters and

safety concerns. Accordingly, high-power single-probe ablative lasers requiring precise aiming are not in the same field of endeavor as multi-probe low-energy therapeutic laser therapy devices.

Additionally, Applicants' invention solves the problem of how to apply multiple low-level laser beams to a patient simultaneously and with freely movable handheld probes. Zavislan's invention does not teach or suggest any solutions because it cannot operate safely or successfully if expanded to multiple handheld probes. Ablative lasers require the operator to pay particular attention to aiming the laser beam at a single tiny treatment area, making it physically impossible to apply more than one ablative laser beam at a time. Otherwise, the operator would inadvertently damage areas not intended to be treated with a first laser while attending to the desired treatment area of a second laser. Only in the movies can a human aim and fire two laser weapons simultaneously at two different microscopic targets and hit them. It would not be reasonable for Applicants to consider destructive technology that is incapable of supporting multi-probe devices when designing a therapeutic multi-probe device.

Because Zavislan involves different types of lasers and because a low-level laser device designer would not look to high-power ablative lasers when designing a multi-probe device, Zavislan is non-analogous art. Accordingly, no *prima facie* case of obviousness has been established.

2. Claims 1-10 and 13-22 are not obvious in light of Gerdes and Zavislan because Zavislan teaches away from using more than one handheld probe.

Each of Applicants' claims 1-10 and 13-22 teaches a device comprising two or more handheld laser probes. Although Gerdes teaches multiple handheld wands,

Zavislan teaches away from multiple wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Zavislan discloses a high power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. Because Zavislan's device causes temperature changes and structural changes in tissue, particular attention to visualizing where the laser beam is applied is critical. As stated in Zavislan:

> It is the principal object of the present invention to provide an improved system for laser assisted microsurgical ... treatments in which the treatment area can be visualized while the laser beam is being located at sites in the area where treatment is desired.

Zavislan, column 2, lines 14-18. It would be impractical, possibly even dangerous, to attempt to apply multiple ablative laser beams simultaneously. Zavislan teaches a device specifically designed to allow the operator to visually aim the laser beam. Zavislan's ablative laser device will fail if it is expanded to multiple handheld probes, especially where they treat different areas simultaneously.

Accordingly, Zavislan teaches away from using multiple handheld laser probes. Because references cannot be combined where one reference teaches away from the combination, Zavislan and Gerdes cannot be combined. No *prima facie* case of obviousness has been established.

3. Claims 1-10 and 13-22 are not obvious in light of Gerdes and Zavislan because the prior art teaches against freely moving the probes.

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 1-10 and 13-22 teach handheld probes that "emit one or more laser beams ... while being freely moved by a user's hand relative to the surface of the skin of a patient." Gerdes and Zavislan each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating the same area of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

As explained above, Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to aim the laser beam accurately. Zavislan, column 1, lines 24-30 and column 2, lines 14-18. It would be

impractical, possibly even dangerous, to freely move one or more ablative laser beams during treatment.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

4. Claim 2 is not obvious in light of Gerdes and Zavislan because the prior art teaches against emitting two laser beams simultaneously and impinging two different parts of a patient's body.

Applicants' Claim 2 requires that "at least two of the laser beams are emitted simultaneously and impinge two different parts of a patient's body." As detailed earlier, Applicants' intend that their invention enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Gerdes and Zavislan each teach away from simultaneously treating two different parts of a patient's body, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Again, Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating the same area of the patient. It would render Gerdes inoperable to modify it such that two laser beams simultaneously

treat different areas of a patient because then the laser beams would not intersect. Thus, Gerdes teaches against the probes simultaneously treating two different areas of a patient's body.

Again, Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to visually aim the laser beam accurately. Zavislan, column 1, lines 24-30 and column 2, lines 14-18. It would render Zavislan inoperable to modify it such that two ablative laser beams treat two different areas simultaneously because then the operator could not visually aim the laser beams. Thus, Zavislan teaches against the probes simultaneously treating two different areas of a patient's body.

Because it is improper to combine references when on teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from simultaneously treating two different parts of the body with two laser beams, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

5. Claim 16 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests using ultraviolet laser light.

Applicants' claim 16 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Ultraviolet light ranges from about 4 nm to 380 nm, just beyond violet in the visible spectrum of light. Neither Gerdes nor

Zavislan disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Zavislan discloses exposing tissue to laser beams having a wavelength from 700 to 1300 nm. Zavislan, column 3, lines 57-60. Zavislan does not disclose or suggest a wavelength of less than 700 nm.

Gerdes discloses exposing tissue to converging beams of treatment (infrared) radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes, column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength of less than 400 nm.

The Examiner alleges on page 4 of his September 28th, 2006 office action that Gerdes discloses 400nm of ultraviolet light at col. 9, line 38. Gerdes actually refers to *visible* light at 400 nm, however. Specifically, the Gerdes cite reads in its entirety:

> Additionally, each of the *visible* laser radiation sources 170 is also configured to emit radiation having a wavelength preferably between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes at column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light. Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Zavislan suggests the use of ultraviolet wavelengths, neither Zavislan nor Gerdes suggests using an ultraviolet wavelength. Lacking any

suggestion or motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

6. Claim 17 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests a linear spot shape.

Applicants' claim 17 requires one of the spot shapes to be substantially linear. Zavislan does not disclose any particular beam shapes. Moreover, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention," a line is not a "spread-out" spot shape in the same sense. See Gerdes, column 9, lines 45-49. The light of Gerdes's "spread out patterns" travel in all directions in the plane of the treatment surface. A linear spot shape, however, is not "spread out" because it travels in only one direction in the plane of the treatment surface, namely along the length of the line. Therefore, Gerdes does not disclose or suggest a line. Lacking any suggestion or motivation of a linear beam shape, no *prima facie* case of obviousness has been made.

7. Claim 19 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests a plus-sign spot shape.

Applicants' claim 19 requires one of the spot shapes to be in the shape of a plus sign. Zavislan does not disclose any particular beam shapes. Moreover, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patters are also suitable for use with the present invention," a plus-sign is not a "spread-out" spot shape. See Gerdes, column 9, lines 45-49. Lacking any suggestion or motivation of a plus-sign spot shape, no *prima facie* case of obviousness has been made.

8. Claim 21 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests different spot shapes.

Applicants' claim 21 requires that the spot shape of a first laser beam to be different from a spot shape of a second laser beam; that is, the first and second beam shapes are different. Again, Zavislan does not disclose any particular beam shapes. While Gerdes discloses that "a wide variety" of "spread-out" beam shapes can be used, Gerdes does not indicate that the beam shapes emitted from the radiation sources can be different from each other. See Gerdes, column 9, lines 45-49. Lacking any suggestion or motivation of two different beam shapes, no *prima facie* case of obviousness has been made.

9. Claims 23-29 are not obvious in light of Gerdes and Zavislan because Zavislan is non-analogous art.

Each of Applicants' claims 23-29 are directed at low-power healing handheld laser probes that are freely moved by a user's hands for healing purposes. While Zavislan teaches a single handheld laser device, it teaches one in an entirely different field and solving an unrelated problem. It is well-settled law that it is improper to consider a reference that is non-analogous. *In re Oeticker*, 24 USPQ2d at 1446.

Applicant's invention is a handheld multi-probe non-ablative laser device for wound healing, edema reduction, pain relief, inflammation reduction, and other similar applications. Pending App. Paragraph [0003], lines 2-6. It uses low-level laser energy and causes no immediate detectable temperature rise and no macroscopically visible changes in tissue structure. Pending App. Paragraph [0004], lines 2-4. The treated and surrounding tissue is neither heated nor damaged. *Id.* Additionally, because no damage occurs where the laser beam is applied, more than one laser can be applied

simultaneously for faster and improved therapy. Pending App. Paragraph [0005], lines 1-6. Precise and accurate aiming of each probe is not critical to successful therapeutic results.

Zavislan discloses a high-power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. A laser treatment with the device disclosed in Zavislan necessarily causes changes a rise in temperature and changes in tissue structure to accomplish necrosis and cauterization. *Id*. In addition, particular attention to visualizing where the laser beam is applied is critical according to Zavislan so that the operator does not damage areas where no treatment is desired. Zavislan, column 2, lines 16-18.

Because therapeutic lasers and surgical lasers result in dramatically different results on a patient's body, they must be designed considering different parameters and safety concerns. Accordingly, high-power single-probe ablative lasers requiring precise aiming are not in the same field of endeavor as multi-probe low-energy therapeutic laser therapy devices.

Additionally, Applicants' invention solves the problem of how to apply multiple low-level laser beams to a patient simultaneously and with freely movable handheld probes. Zavislan's invention does not teach or suggest any solutions because it cannot operate safely or successfully if expanded to multiple handheld probes. The arguments of Section VII.D.2 are incorporated herein. Ablative lasers require the operator to pay particular attention to aiming the laser beam accurately, making it impossible to apply

more than one ablative laser beam at a time. It would not be reasonable for Applicants to consider destructive technology incapable of supporting multi-probe devices when designing a multi-probe therapeutic device.

Because Zavislan involves different types of lasers and because a low-level laser device designer would not look to high-power ablative lasers when designing a multi-probe device, Zavislan is non-analogous art. Accordingly, no *prima facie* case of obviousness has been established.

10. Claims 23-29 are not obvious in light of Gerdes and Zavislan because Zavislan teaches away from using more than one handheld probe.

Each of Applicants' claims 23-29 teaches a device comprising two or more handheld laser probes. Although Zavislan teaches multiple handheld wands, Zavislan teaches away from multiple wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Zavislan discloses a high power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. Because Zavislan's device causes temperature changes and structural changes in tissue, particular attention to visualizing where the laser beam is applied is critical. As stated in Zavislan:

> It is the principal object of the present invention to provide an improved system for laser assisted microsurgical ... treatments in which the treatment area can be visualized while the laser beam is being located at sites in the area where treatment is desired.

Zavislan, column 2, lines 14-18. It would be impractical, possibly even dangerous, to attempt to apply multiple ablative laser beams simultaneously. Zavislan teaches a device specifically designed to allow the operator to visually aim the laser beam. Zavislan's ablative laser device will fail if it is expanded to multiple handheld probes, especially where they treat different areas simultaneously.

Accordingly, Zavislan teaches away from using multiple handheld laser probes. Because references cannot be combined where one reference teaches away from the combination, Zavislan and Gerdes cannot be combined. No *prima facie* case of obviousness has been established.

11. Claims 23-29 are not obvious in light of Gerdes and Zavislan because the prior art teaches against freely moving the probes.

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 23-29 teach handheld probes that "emit one or more laser beams ... while being freely moved by a user's hand relative to the surface of the skin of a patient." Gerdes and Zavislan each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating the same area of the patient. It would

render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to aim the laser beam accurately. Zavislan, column 1, lines 24-30 and column 2, lines 14-18. It would be impractical, possibly even dangerous, to freely move multiple ablative laser beams during treatment.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

12. Claim 29 is not obvious in light of Gerdes and Zavislan because neither Gerdes nor Zavislan suggests using ultraviolet laser light.

Applicants' claim 29 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Ultraviolet light ranges from about 4 nm to 380 nm, just beyond violet in the visible spectrum of light. Neither Gerdes nor Zavislan disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Zavislan discloses exposing tissue to laser beams having a wavelength from 700 to 1300 nm. Zavislan, column 3, lines 57-60. Zavislan does not disclose or suggest a wavelength of less than 700 nm.

Gerdes discloses exposing tissue to converging beams of treatment (infrared radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength of less than 400 nm.

The Examiner alleges on page 4 of his September 28, 2006 office action that Gerdes discloses 400nm of ultraviolet light at col. 9, line 38. Gerdes actually refers to *visible* light at 400 nm, however. Specifically, the Gerdes cite reads in its entirety:

> Additionally, each of the *visible* laser radiation sources 170 is also configured to emit radiation having a wavelength preferably between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes at column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light. Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Zavislan suggests the use of ultraviolet wavelengths, neither Zavislan nor Gerdes suggests using an ultraviolet wavelength. Lacking any suggestion of motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

13. Claims 30 and 32 are not obvious in light of Gerdes and Zavislan because Zavislan is non-analogous art.

Each of Applicants' claims 30 and 32 are directed at low-power healing handheld laser probes that are freely moved by a user's hands for healing purposes. While Zavislan teaches a single handheld laser device, it teaches one in an entirely different field and solving an unrelated problem. It is well-settled law that it is improper to consider a reference that is non-analogous. *In re Oeticker*, 24 USPQ2d at 1446.

Applicant's invention is a handheld multi-probe non-ablative laser device for wound healing, edema reduction, pain relief, inflammation reduction, and other similar applications. Pending App. Paragraph [0003], lines 2-6. It uses low-level laser energy and causes no immediate detectable temperature rise and no macroscopically visible changes in tissue structure. Pending App. Paragraph [0004], lines 2-4. The treated and surrounding tissue is neither heated nor damaged. *Id.* Additionally, because no damage occurs where the laser beam is applied, more than one laser can be applied simultaneously for faster and improved therapy. Pending App. Paragraph [0005], lines 1-6. Precise and accurate aiming of each probe is not critical to successful therapeutic results.

Zavislan discloses a high-power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. A laser treatment with the device disclosed in Zavislan necessarily causes changes in tissue structure and temperature rises. In addition, particular attention to visualizing where the laser beam is applied is critical

according to Zavislan so that the operator does not damage areas where no treatment is desired. Zavislan, column 2, lines 16-18.

Because therapeutic lasers and surgical lasers result in dramatically different results on a patient's body, they must be designed considering different parameters and safety concerns. Accordingly, high-power single-probe ablative lasers requiring precise aiming are not in the same field of endeavor as multi-probe low-energy therapeutic laser therapy devices.

Additionally, Applicants' invention solves the problem of how to apply multiple low-level laser beams to a patient simultaneously and with freely movable handheld probes. Zavislan's invention does not teach or suggest any solutions because it cannot operate safely or successfully if expanded to multiple handheld probes. Ablative lasers require the operator to pay particular attention to aiming and focusing the laser beam accurately, making it impossible to apply more than one ablative laser beam at a time. It would not be reasonable for Applicants to consider technology incapable of supporting multi-probe devices when designing a therapeutic device for treating multiple areas simultaneously with non-ablative lasers.

Because Zavislan involves different types of lasers and because a low-level laser device designer would not look to high-power ablative lasers when designing a multi-probe device, Zavislan is non-analogous art. Accordingly, no *prima facie* case of obviousness has been established.

14. Claims 30 and 32 are not obvious in light of Gerdes and Zavislan because Zavislan teaches away from using more than one handheld probe.

Each of Applicants' claims 30 and 32 teaches a device comprising two or more handheld laser probes. Although Zavislan teaches multiple handheld wands, Zavislan teaches away from multiple wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Zavislan discloses a high power laser for microsurgical treatments in dermatology. Zavislan, column 1, lines 8-11. Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath. Zavislan, column 1, lines 24-30. Because Zavislan's device causes temperature changes and structural changes in tissue, particular attention to visualizing where the laser beam is applied is critical. As stated in Zavislan:

> It is the principal object of the present invention to provide an improved system for laser assisted microsurgical ... treatments in which the treatment area can be visualized while the laser beam is being located at sites in the area where treatment is desired.

Zavislan, column 2, lines 14-18. It would be impractical, possibly even dangerous, to attempt to apply multiple ablative laser beams simultaneously. Zavislan teaches a device specifically designed to allow the operator to visually aim the laser beam. Zavislan's ablative laser device will fail if it is expanded to multiple handheld probes, especially where they treat different areas simultaneously.

Accordingly, Zavislan teaches away from using multiple handheld laser probes. Because references cannot be combined where one reference teaches away from the

combination, Zavislan and Gerdes cannot be combined. No *prima facie* case of obviousness has been established.

15. Claims 30 and 32 are not obvious in light of Gerdes and Zavislan because the prior art teaches against freely moving the probes.

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 30 and 32 teach handheld probes that "emit one or more laser beams ... while being freely moved by a user's hand relative to the surface of the skin of a patient." Gerdes and Zavislan each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. See Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically for the laser beams to intersect, the wands must be treating substantially the same area of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Zavislan teaches a device wherein the wand is visually positioned over a treatment area where microsurgery is desired. Because Zavislan's laser device is ablative, causing destruction of spider veins, hair follicles, and adhesions between tendons and their surrounding sheath, it is critical to aim the laser beam accurately. Zavislan, column 1,

TITLE

Multi-Probe Laser Device

FIELD OF INVENTION

[0001] This invention relates generally to medical devices that employ lasers. More particularly, this invention relates to a laser light generator device that has multiple probes, enabling multiple different treatments to be made simultaneously.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0002] This application claims the benefit of co-pending U.S. Application No. 09/932,907 filed 08/20/2001 which claims the benefit of U.S. Provisional Application No. 60/273,282 filed March 2, 2001.

BACKGROUND

[0003] Low energy laser therapy (LLLT) is used in the treatment of a broad range of conditions. LLLT improves wound healing, reduces edema, and relieves pain of various etiologies, including successful application post-operatively to liposuction to reduce inflammation and pain. LLLT is also used during liposuction procedures to facilitate removal of fat by causing intracellular fat to be released into the interstice. It is also used in the treatment and repair of injured muscles and tendons.

[0004] LLLT utilizes low level laser energy, that is, the treatment has a dose rate that causes no immediate detectable temperature rise of the treated tissue and no macroscopically visible changes in tissue structure. Consequently, the treated and surrounding tissue is not heated and is not damaged. There are a number of variables in laser therapy including the wavelength of the laser beam, the area impinged by the laser beam, laser energy, pulse width, treatment duration and tissue characteristics. The success of each therapy depends on the relationship and combination of these variables. For example, liposuction may be facilitated with one regimen utilizing a given wavelength and treatment duration, whereas pain may be treated with a regimen utilizing a different wavelength and treatment duration, and inflammation a third regimen. Specific devices are known in the art for each type of therapy.

Appendix R-6

[0005] Often it is desirable to treat a patient for multiple types of problems during a single treatment. Because specific therapies require different regimen, treating multiple problems currently requires multiple separate laser devices. It is desirable to provide a device that enables multiple types of treatments with a single device. It is also desirable to be able to provide multiple treatments simultaneously with a single device, in different areas of a patient's body.

[0006] Therefore, an object of this invention is to provide a laser therapy device that enables multiple types of treatments. It is another object to provide a single device that provides these treatments simultaneously. It is another object of this invention to provide an apparatus that can simultaneously emit multiple beams of laser light that can be applied to multiple areas of a patient's body. It is another object of this invention to provide an apparatus that can simultaneously emit laser light in multiple different pulse widths. It is a further object of this invention to provide an apparatus that can simultaneously emit laser light in multiple beam shapes and spot sizes. It is a particular object of this invention to provide a hand-held therapeutic laser device to provide low level laser therapy which can be used to simultaneously facilitate liposuction, treat post-operative inflammation and pain, and treat and repair injured muscles and tendons.

SUMMARY OF THE INVENTION

[0007] This invention is an improved hand-held laser device that can simultaneously provide multiple types of low level laser therapy treatments to multiple areas of a patient's body simultaneously. The device enables laser light of different pulse widths, different beam shapes and spot sizes to be applied to a patient's body. The device includes multiple laser sources. In the preferred embodiment, two semiconductor diode laser sources simultaneously provide two separate laser beams from separate probes, one laser beam producing laser light at a first pulse width and the other producing laser light at a second pulse width.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a schematic illustration of a preferred embodiment of the present invention.

[0009] FIG. 2 is a schematic view of the optical arrangement producing a line spot shape of the preferred embodiment.

[0010] FIG. 3 is a schematic view of the optical arrangement producing a circular spot shape of the preferred embodiment.

[0011] FIG 4 is a schematic illustration of a preferred embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0012] FIG 5 is a schematic illustration of an alternate embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0013] FIG. 6 is a schematic illustration of an alternate embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0014] FIG. 7 is a schematic illustration of application of low-level laser radiation using the preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0015] Referring to the drawings, there is illustrated a hand-held laser device designated generally as 10. The device includes one or more laser energy sources, a power source, at least two optical arrangements, one or more control circuits, and at least two hand-held aiming devices, referred to herein as probes. Fig. 1 shows the preferred embodiment in which a first probe 11 and a second probe 12 are connected to a base 14, which includes a power source 15 (not shown). The base 14 is typically a hand-held unit, but it may also be a stationary unit that typically sits on a table or the ground, functioning as a central base from which many probes may be employed.

[0016] The preferred embodiment comprises a first laser energy source 21 for emitting light from the first probe 11 and a second laser energy source 22 for emitting light from the second probe 12. The laser energy sources 21 and 22 are connected to the power source 15. The power source preferably provides direct current, such as that provided by a battery, but may instead provide alternating current such as that provided by conventional building current which is then converted to direct current. These laser energy sources can be energized independently or simultaneously, which throughout this specification refers to acts occurring at generally at the same time.

[0017] The first laser energy source 21 and second laser energy source 22 each produce a laser beam which exits the laser and is shone through optical arrangements 41 and 42, respectively, that produce beam spots. The beam spot is the cross-sectional shape and size of the emitted beam as it exits the optical arrangement. For example, a laser beam of circular cross-section creates a circular beam spot as the laser light impinges the patient's skin. If the laser light emitted is in the visible range, a circular spot can be seen on the patient's skin of substantially the same diameter as the laser beam emitted from the optics arrangement. Various beam spot shapes can be created, including a line, a circle, an ellipse, a plus-sign, or combination of any of them. The probes may product different spot shapes, or have the same spot shapes.

[0018] In the preferred embodiment, the first laser beam is passed through a first optical arrangement that generates a beam of substantially linear cross-section, resulting in a line of laser light seen on the patient's skin. The second laser passes through a second optical arrangement that generates a beam of circular cross-section, resulting in a circular spot shape as seen on the patient's skin. Fig. 2 illustrates the first optical arrangement 41 of the preferred device, which includes a collimating lens 44 and a line generating prism 45. The collimating lens 44 and the line generating prism 45 are disposed in serial relation to the laser energy source 21. The collimating lens 44 and the line generating prism 45 receive and transform the generated beam of laser light into the line of laser light L. As an alternative, a suitable electrical or mechanical arrangement could be substituted for the optical arrangement 41.

[0019] As shown in Fig. 3 the second optical arrangement 42 of the preferred device includes a collimating lens 46 and a beam spot shaping lens 47. As with the first optical arrangement, the collimating lens 46 and beam spot shaping lens 47 are disposed in serial relation to the second laser energy source 22. The collimating lens 46 and beam spot shaping lens 47 receive and transform the generated beam of laser light into a circular beam spot of laser light C. As an alternative, a suitable electrical or mechanical arrangement could be substituted for the optical arrangement 42 to achieve a desired spot shape.

[0020] Control circuitry is connected to the laser energy sources to control whether the lasers are on or off, how long the lasers are powered on, the duration of each pulse of

laser light emitted, and the period of time between one pulse starting and the next pulse starting, referred to herein as the pulse width. Typically the control circuitry is digital, in discrete or integrated circuits, as is known in the art, but analog circuits can also be employed. In the preferred embodiment there are separate control circuits for each probe. Control circuits 31 and 32 are connected to the laser energy sources 21 and 22, respectively, to control the various parameters of the emissions. For ease of reference, pulse widths can be referred to in shorthand notation in cycles/second, or Hz. Pulse widths from 0 to 100,000 Hz may be employed to achieve the desired effect on the patient's tissue. At 100,000 Hz, the pulse width is 0.00001 second. At 0 Hz, a continuous beam of laser light is generated. The goal for LLLT regimen is to deliver laser energy to the target tissue utilizing a pulse width short enough to sufficiently energize the targeted tissue and avoid thermal damage to adjacent tissue.

[00021] The probes have an interior cavity. In the preferred embodiment, the first laser energy source 21 and first optical arrangement 41 are contained in the first probe 11 and the second laser energy source 22 and second optical arrangement 42 are contained in the second probe 12, while the power source 15 and control circuitry 31 and 32 are contained within the base 14. See Fig. 4, which illustrates the configuration of the components of the invention as they relate to each probe, and where the dotted line 17 indicates the components disposed in the first probe and dotted line 18 indicates the components disposed in the second probe. Alternatively, the laser energy source, optical arrangement, and control circuitry can be housed in the probe. That is, the first laser energy source 21, the first optical arrangement 41, and the control circuitry for the first probe 31 are contained in the first probe 11, and the second laser energy source 22, the second optical arrangement 42, and the control circuitry for the second probe 32 are contained in the second probe 12, as the power source 15 remains within the base 14. See Fig. 5 in which dotted lines 17 and 18 again indicate the components that are in the probes. Fig. 6 shows another alternate configuration, in which a single laser energy source 23, a single control circuitry 33 for the first probe and the second probe, and the power source 15 are contained in the base 14, and the probes contain only the optical arrangement for the first probe 41 and the optical arrangement for the second probe 42,

respectively. Again, the dotted lines 17 and 18 indicate which components are in the probes.

[0022] Laser energy sources are known in the art for use in low-level laser therapy. Visible light in about the 400-700 nm range is preferred, and the frequency is determined by the particular therapy given to the patient. The laser energy sources include Helium-Neon lasers having a 632 nm wavelength and semiconductor diode lasers with a broad range of wavelengths between about 600-800 nm. The laser energy sources in the preferred embodiment are two semiconductor laser diodes that produce light in the red range of the visible spectrum, having a wavelength of about 635 nm. Other suitable wavelengths are used for other particular applications. While many LLLT regimen include visible laser light, it may be advantageous to utilize ultraviolet (approx. 1-400 nm) or infrared (approx 700 – 10^5 nm) laser energy, again depending on the type of treatment desired. Solid state and tunable semiconductor laser diodes may also be employed to achieve the desired wavelength.

[0023] Different therapy regimens require diodes of different wattages. The preferred laser diodes use less than one watt of power each to simultaneously facilitate liposuction, treat post-operative inflammation, and post-operative pain. Diodes of various other wattages may also be employed to achieve the desired laser energy for the given regimen.

[0024] Fig. 7 illustrates the device in use. A practitioner 70 treats one area of the patient 71 with the first probe 11 and treats a different area of the patient 71 with the second probe 12.

[0025] While there has been illustrated and described what is at present considered to be a preferred embodiment of the present invention, it will be understood by those skilled in the art that various changes and modifications may be made, and equivalents may be substituted for elements thereof without departing from the true scope of the invention. Therefore, it is intended that this invention not be limited to the particular embodiment disclosed as the best mode contemplated for carrying out the invention, but that the invention will include all embodiments falling within the scope of the appended claims.

ABSTRACT

A hand-held laser device that can simultaneously provide multiple types of low level laser therapy treatments to multiple areas of a patient's body simultaneously. The device enables laser light of different pulse widths, different beam shapes and spot sizes to be applied to a patient's body. The device includes multiple laser sources. In the preferred embodiment, two semiconductor diode laser sources simultaneously provide two separate laser beams from separate probes, one laser beam producing laser light at a first pulse width and the other producing laser light at a second pulse width.

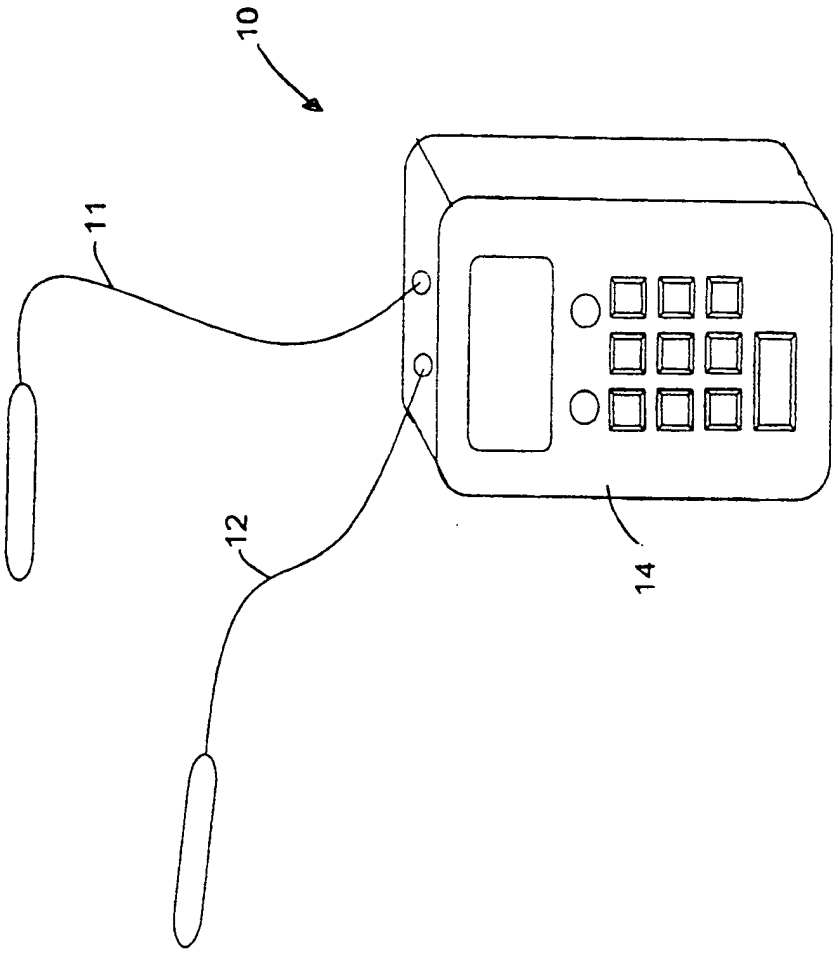

FIG. 1

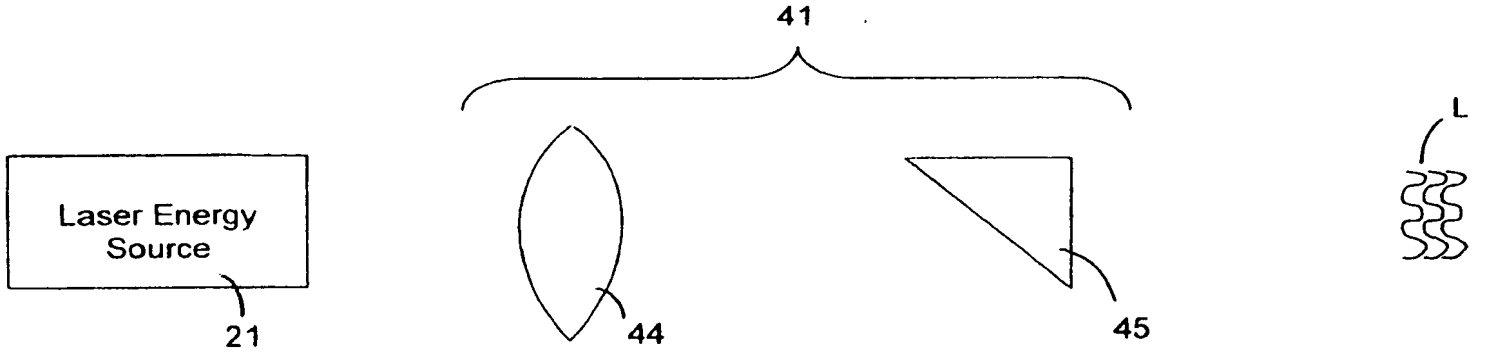
41
Laser Energy Source
21
44
45
L

FIG. 2

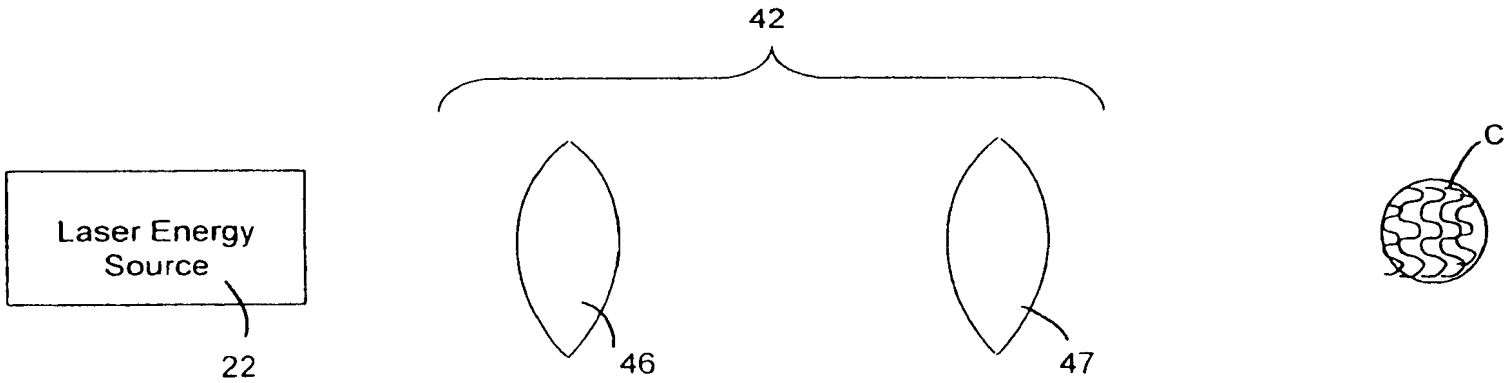
42
Laser Energy Source
22
46
47
C

FIG. 3

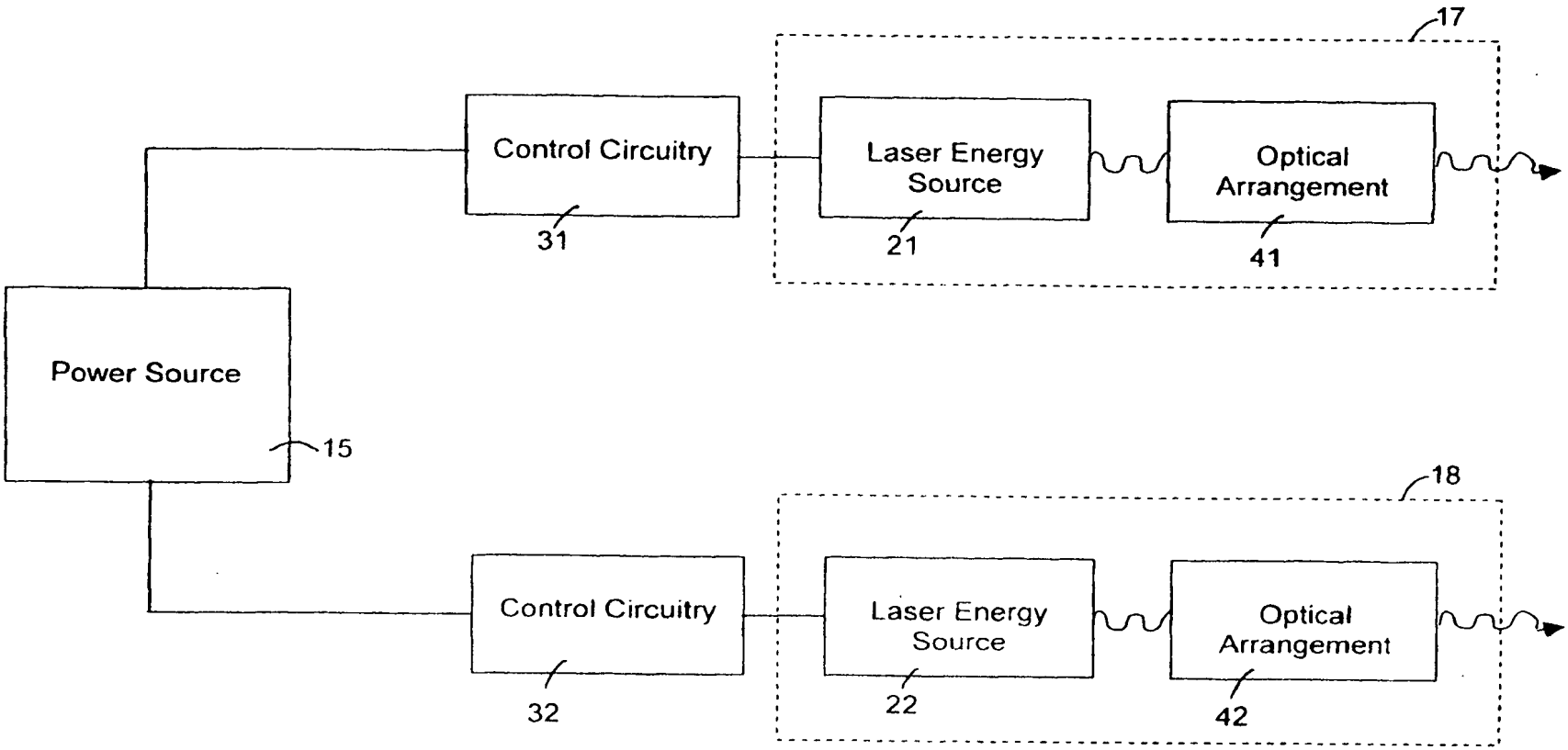
17
Control Circuitry
Laser Energy Source
Optical Arrangement
31
21
41
Power Source
15
18
Control Circuitry
Laser Energy Source
Optical Arrangement
32
22
42

FIG. 4

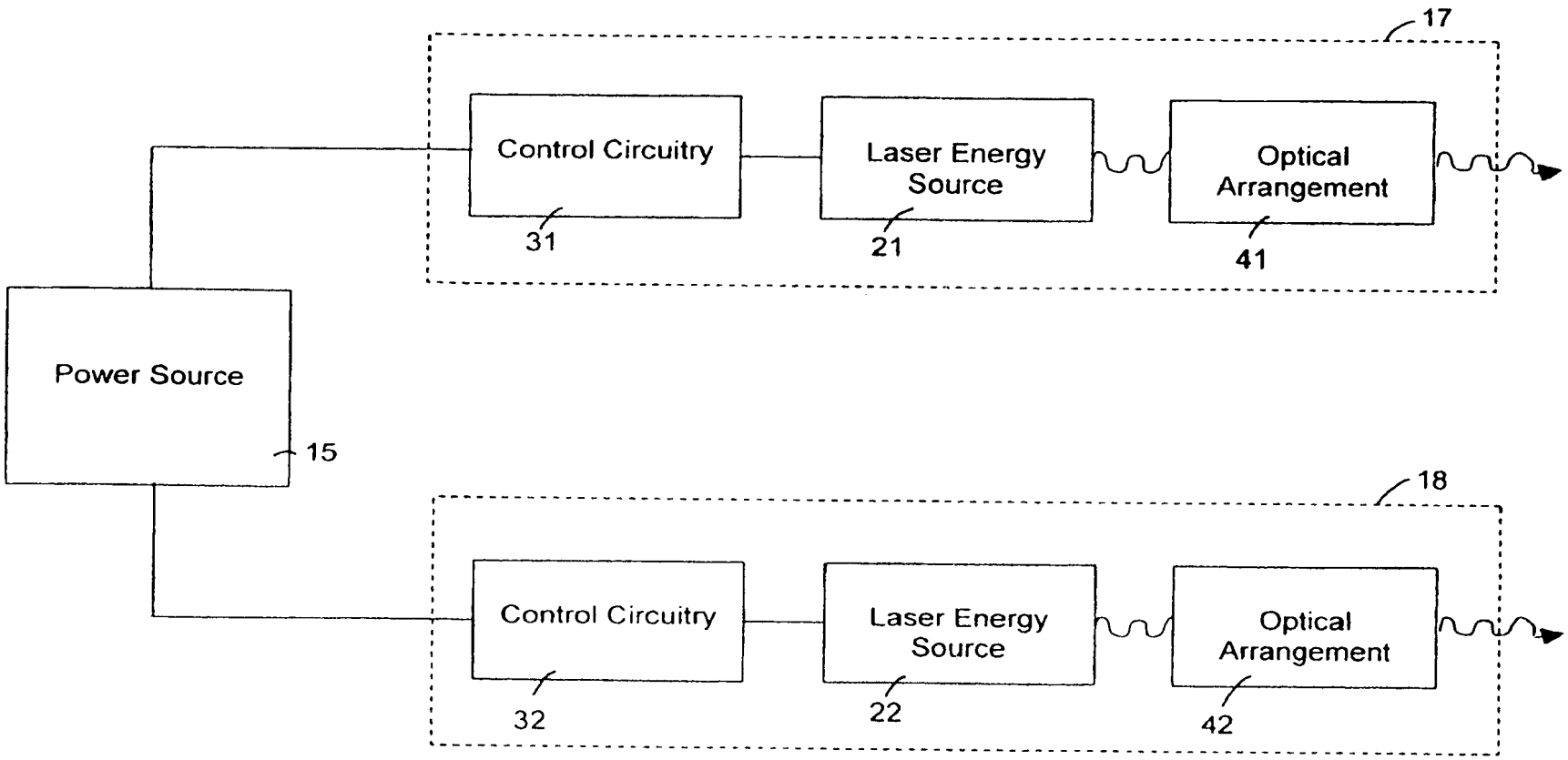
17
Control Circuitry
Laser Energy Source
Optical Arrangement
31
21
41
Power Source
15
18
Control Circuitry
Laser Energy Source
Optical Arrangement
32
22
42

FIG. 5

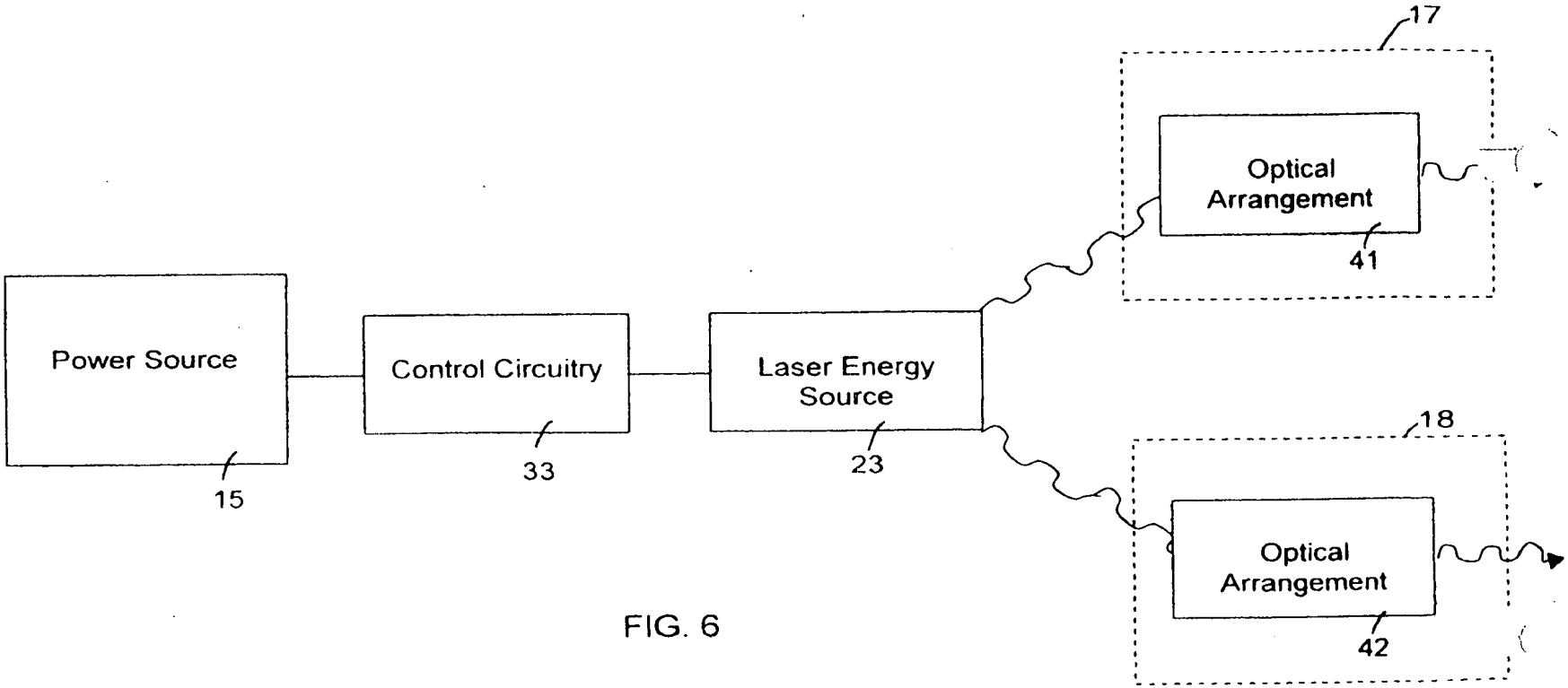
17
Optical Arrangement
41
Power Source
Control Circuitry
Laser Energy Source
18
Optical Arrangement
42
15
33
23

FIG. 6

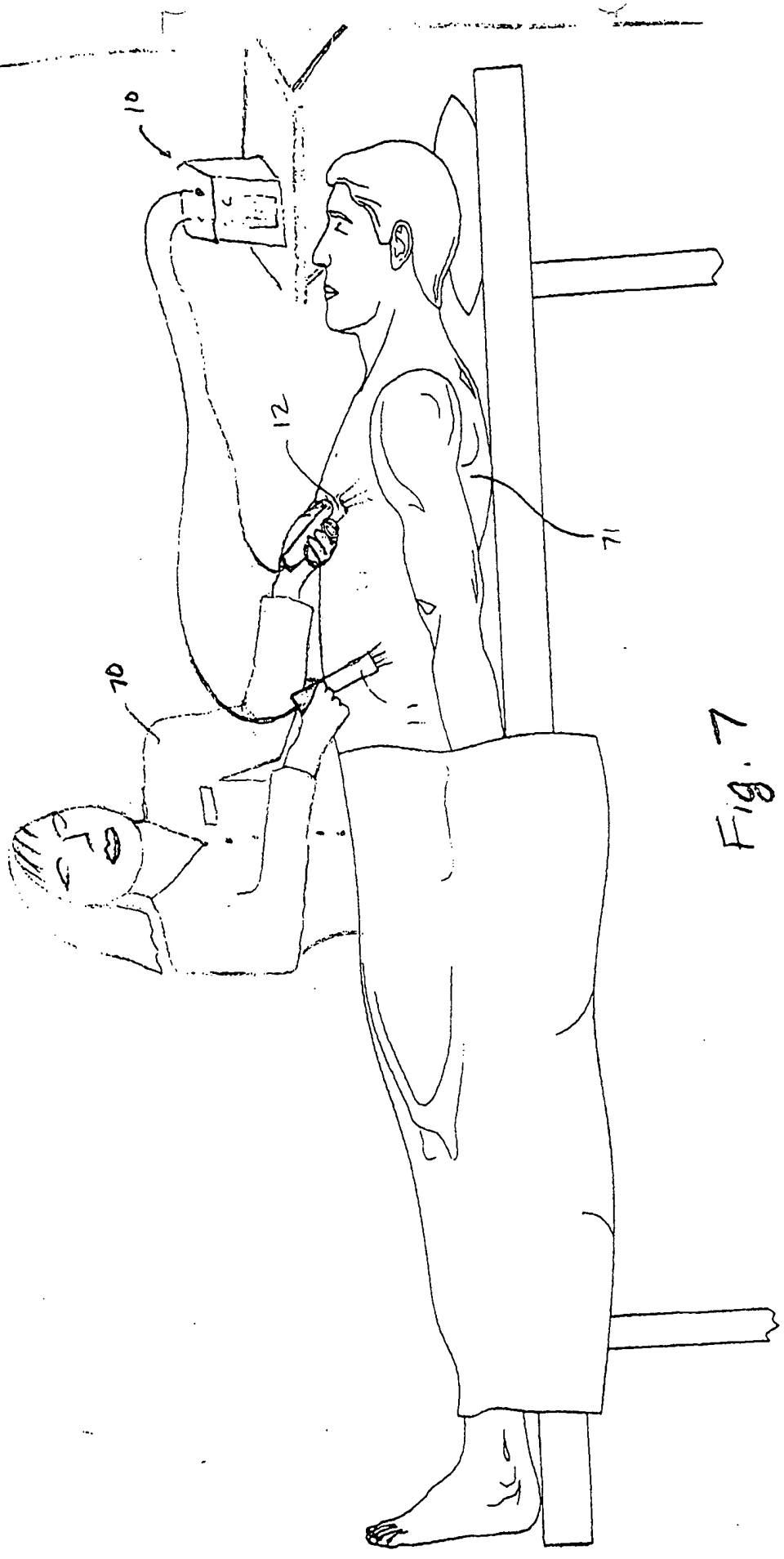

Fig. 7

lines 24-30 and column 2, lines 14-18. It would be impractical, possibly even dangerous, to freely move one or more ablative laser beams during treatment.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Gerdes and Zavislan cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

Conclusion

Applicants have shown that Claims 1-10, 13-30, and 32 are not obvious under 35 USC 103(a) in light of Gerdes and Zavislan for one or more reasons explained above. Reversal of the rejections is respectfully requested.

VIII. Conclusion

Applicants believe they have shown that none of the Examiner's rejections in the pending application should be sustained. Applicants respectfully request that the Board reverse all the Examiner's rejections and allow the case to proceed to issuance.

Respectfully submitted,

Date: 3/4/07

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